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A multidisciplinary pelvic floor journal

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Editorial

Pelviperineology 2012 editorial lines

Pelviperineology publishes original articles devoted to the study of the ***pelvic floor as an integrated system*** *highlighting the point of view of different specialists in urology, gynaecology and colorectal surgery. Articles should contain the most recent references and* ***state of the art*** *in problems concerning the pelvic area. The journal welcomes as well articles that may update* ***non specialists*** *in this field, for example internal medicine physicians, family doctors, neurologists, etc., about conditions of general interest involving the pelvic floor and how they can be resolved with a multidisciplinary approach.*

The ideal article for Pelviperineology should be clear: its sections should describe precisely the methodology of the study and the statistical methods; illustrations must be of good quality. In the case of highly specialized topics, an easy understandable abstract, a good introduction and a correct sections distribution are particularly appreciated.

Pelviperineology aims to open an ***imaging section*** *presenting clinically relevant data with a short commentary. As well, there will be a* ***clinical cases section*** *demonstrating typical cases of general interest and the best way to manage them.*

In order to reduce the time between the article being accepted and published, Pelviperineology will start an ***"in press" section*** *allowing immediate viewing of the articles planned for publication.*

Articles submitted to Pelviperineology will be mailed, without identification of the Authors, to three independent Referees who will give a synthetic evaluation with notes to the Authors when needed.

The Editor in charge will consider the Referees' opinion before making a final decision on publication. If necessary the Authors may be asked to review their manuscript and/or to answer to the Referees' notes. The whole Peer Review process may be entirely followed online.

Following the publication of issue 1, 2012, all articles for Pelviperineology will be processed entirely through the web based software ***Isubmit*** *(www.isubmit.it). Full instructions will be published in the journal pages. Our goal is a collaborative platform based on the software* Isubmit*, allowing reviewers and Authors to work together to obtain the best quality publication.*

This new system will allow Authors to submit new articles, to review their list of previous articles, their status (awaiting for review, under review, accepted, etc), to automatically create a pdf version, and to correct it directly on line where necessary.

The Isubmit *system will enable Pelviperineology to communicate to the Author the final decision* ***within 30 days from submission****. The system can certify the day when an article has been submitted to the Journal. The register of this certification has legal value in some countries. An acknowledgment will be sent via email to the Author at submission. A similar receipt will be sent when the article is accepted.*

In the near future, Isubmit *will automatically perform part of the work required to prepare the text for printing on paper and online, and this will facilitate the publication of accepted articles in the website "in press" section. These articles are not copy edited and may lead to small differences with the final version. There may also be differences in the quality of the graphics. Once the papers appear in print, they will be removed from the "in press" and they will carry below each title the "Papers in press" publication date.*

Isubmit *will also allow Pelviperineology a more efficient management of the editorial process, reducing the publication cost. This will help to continue the present "open access" philosophy of the journal, without any cost to the Authors.*

Welcome to the new Pelviperineology!

Editorial

Urogynecology in China

Though the International Urogynecology Society has been established for many years, Chinese doctors adopted a more organized approach to modern pelvic floor reconstruction, dates from the year 2000. Prior to this, Chinese doctors had been engaged in pelvic surgery, such as anti-incontinence surgery (for example, transabdominal or laparoscopic Burch surgery), vaginal hysterectomy for uterine prolapse, anterior and posterior vaginal wall repair for vaginal prolapse, Manchester Repair surgery and Le Fort surgery. In 1950s and 1960s, Chinese doctors launched a large-scale surgery for pelvic floor prolapse and reproductive tract fistula, and accumulated rich experience. Since 2000, Chinese doctors have come to realize the link between these diseases and pelvic floor dysfunction (PFD), and accepted the concept of pelvic floor reconstruction. Some hospitals, such as Shanghai Jiaotong University Affiliated Sixth People's Hospital, Beijing Union Medical College Hospital and the Fuzhou General Hospital of Nanjing Military command, initially carried out the female pelvic floor reconstruction surgery in China. They began to perform pelvic floor reconstruction surgery using polypropylene mesh and sling, carried out basic research on PFD.

In 2004, China held the First National Conference of Urogynecology. In 2005, an official society, the Chinese Medical Association Urogynecology Society established. The society engaged in promoting new theory and technology of pelvic floor reconstruction to Chinese doctors. The society also held national academic conference of Urogynecology every two years to exchange experiences and promote new theories and technologies, and organized Urogynecology Continue Medical Education (CME) courses every year. In 2007, Shanghai Jiaotong University affiliated Sixth People's Hospital. Professor Luo Laimin et al translated and published the book named "The Female Pelvic Floor-Function, Dysfunction and Management according to the Integral Theory", written by the Australian Urogynecologist Professor Peter Petros. This book became a professional theory guide for the Chinese Urogynecologist.

Nowadays, the concept of Urogynecology was widely accepted in China. Chinese doctors also do large number of academic research every year. China has completed a national epidemiological survey, and showed that China's incidence rate of adult female urinary incontinence is 30.9%. Our basic studies have shown that both damage of pelvic floor ligaments and muscles lead to SUI and POP. Chinese scholars confirmed the specifically pelvic floor blood vessels and nerves anatomy to ensure the effectiveness and safety of reconstructive surgery. We also do some research of pelvic floor regenerative medicine. Meanwhile, the Chinese doctors also actively participate in IUGA and ICS Annual Meeting. Every year there were some Chinese doctors giving oral and poster presentation at these meetings. Many educational courses of IUGA and ICS were held in these years in China.

The career of Chinese Urogynecology is booming and growing. In 2012, the 42nd Annual Meeting of ICS will be held in Beijing, China. Chinese Urogynecologists hope to build cooperation, communication and further integration into the international Urogynecology family.

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Original article

Is there any difference? A prospective, multicenter, randomized, single blinded clinical trial, comparing TVT with TVT-O (POLTOS study) in management of stress urinary incontinence. Short-term outcomes

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Abstract: *Objective:* to compare effectiveness and safety of tension-free vaginal tape (TVT) and tension-free obturator tape (TVT-O) in surgical treatment of stress urinary incontinence (SUI). *Materials and Methods:* A prospective, multicenter, randomized, single blinded trial. 51 patients were screened and 35 patients were randomly allocated to either TVT (n=19) or TVT-O (n=16) group. *Results:* At 6 months' follow-up, we demonstrated that TVT and TVT-O seems to be equally effective in surgical treatment of SUI. For estimated objective efficacy, pad and cough tests were performed. There were no statistical differences between two procedures. There were no statistical differences between two groups when comparing early (postoperative) and late complications. Average operation time was shorter for TVT-O group, with statistical significance difference between two procedures. *Conclusion:* There appears to be equal efficacy of TVT and TVT-O in surgical treatment of female SUI.

Key words: Transobturator tapes; Short term follow-up; Stress urinary incontinence; Suburethral tape.

INTRODUCTION

Stress urinary incontinence (SUI) is defined as involuntary loss of urine associated with activities increasing intraabdominal pressure, such as coughing, laughing, sneezing or performing the Valsalva maneuver,[1] affecting up to 65% of women aged 45-49.[2]

Many surgical approaches for SUI treatment have been suggested, with different level of success. Until the mid-1990s the gold standard was Burch colposuspension.[3] Currently, mid-urethral sling procedures are considered to be the first line of surgical treatment for the SUI. The tension-free vaginal tape (TVT) procedure was first described by Ulmsten in 1996[4] and is known to be associated with a cure rate between 80 and 90%.[5] Although TVT is a technique considered minimally invasive there are numerous publications on its complications including: bladder perforations (3.8-6.5%), bleeding (1.9-2.7%), mesh erosion (0.9%), and bowel perforations (0.3%).[6,7] To minimize these complications in 2001 Delorme described a method of placing a synthetic polypropylene mesh via transobturator route from the outside to the inside with cured rate almost 90%.[8] In 2003 de Leval described a technique, in which the tape is passed through the obturator foramen from the inside to the outside, called tension-free obturator tape TVT-O.[9]

These transobturator approaches, seem to be safer for the patient, because they decrease the risk of bladder and/or bowel injury and postoperative hemorrhage. Several randomized, controlled trials in the literature compared TVT with TVT-O and other methods of surgical SUI treatment. There are also two meta-analyses[10,11] but there can be some problems with drawing evident conclusions from them, such as methodology or inclusion criteria of the trials that where included. In contrast to those trials, this trial was designed as a single blinded trial, where a patient did not know which procedure is undertaken, which helped us avoid bias. This prospective randomized single blinded trial was designed to compare the use of TVT and TVT-O in surgical treatment of stress urinary incontinence in terms of subjective evaluation of SUI symptoms regression, regression of ailments corresponding with SUI and subjective assessment of health condition after operation. Additionally, the trial included estimation of differences in objective demission of SUI symptoms measured by pad test and cough test, evaluation of quality of life after operation, differences in time of procedure, complications and time of hospitalization.

PATIENTS AND METHODS

Between October 2006 and October 2009, after approval from local ethics committee (06/2006), Caucasian women with SUI symptoms, who were not surgically treated before, were invited to participate in the study. Fifty-one women were screened by 3 centers in Warsaw. All patients gave verbal and written consent. Inclusion criteria included: women aged 40 - 80, SUI confirmed with 1-hour pad-weighing test and positive results of urodynamic tests, maximum bladder volume over 300 ml, patients without urinary tract infection. Exclusion criteria were: BMI over 33 kg/m^2, pathology in the reproductive organ or in lower pelvis which should be qualified for surgical treatment, bladder pathology, hysterectomy with or without salpingectomy in the past, neurological urinary incontinence, overactive bladder, hypotony of detrusor muscle or any form of mixed incontinence, pregnancy, radiotherapy of pelvis in the past, hypersensitivity to anesthetic drugs, post voiding volume >150ml, pelvic organ prolapse, myocardial infarction or hemorrhagic or ischemic stroke within past 6 months prior to randomization, auto immunologic disorders, cancer disease, family of investigator.

Fifty-one patients were primary screened, but 35 patients fulfilled inclusion criteria and were randomized 1:1 to undergo TVT or TVT-O procedure. The randomization was done through a web page secured with a 128-bit code.

In order to increase credibility of the trial, during the whole trial, patients were not informed which type of operation was performed. Due to the fact that TVT and TVT-O

procedure differs in technique and places of skin incisions, every patient had extra skin incisions for masking the type of procedure ("sham operation"). Each patient had 4 skin incisions in localization typical for needle introduced in TVT and TVT-O procedure. Finally 35 patients were randomized to either TVT (n=19) or TVT-O (n=16) group.

The surgical procedures have been described previously.[4,12] In the TVT group, cystoscopy was routinely performed. In both procedures the needles and woven polypropylene tape were Gynecere products (Gynecere Ethicon Inc., Somerville, NJ, USA). The procedures were conducted under spinal anesthesia.

The primary outcome measure was to estimate effectiveness of procedure by measuring subjective regression of SUI symptoms after TVT or TVT-O, before and after 3 and 6 months from operation. To estimate this outcome VAS was used, where zero means no urinary problems and 10 means unbearable urinary complaints. The patients were also asked for subjective estimation of ailments corresponding to SUI and subjective assessment of health condition before and after 3 and 6 months from operation.

The secondary outcome measure was to estimate differences in TVT or TVT-O procedures with regard to: effectiveness of procedure based on objective demission of SUI symptoms, evaluated by pad test before and after 6 months from operation and cough test after 3 and 6 months, evaluation of life quality after 3 and 6 months, differences in time of procedure, complications after each procedure and time of hospitalization.

To estimate life quality of the patients before and after operation, all patients filled in King's Health questionnaire (KHQ) and SF-36 questionnaire.[13,14] Because the KHQ was not translated into Polish in accordance with the principle of „cross-culture translation" and did not undergo appropriate validation under Polish conditions, fully validated SF-36 questionnaire was used, for extra estimation of life quality of patients.

Cough test was performed in recumbence and standing position. Pad test was performed according to ICS (International Continence Society) guidelines.

Operative data such as operative time, estimated intraoperative blood loss, operative complications and the time of hospitalization after procedure were recorded. Due to the fact that, there are different ways to define length of the procedure time in clinical trials, we made a distinction between surgical procedure time, defined as time from first incision till the last suture was made, and operation time, which was defined as time from patient's arrival at operating room to her transfer to the gynecological department. Statistical analysis was performed according to intention to threat (ITT). Analysis of results was performed based on primary and secondary outcome. The differences between both groups were tested. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) v. 10.0. Parameters with normal distribution were evaluated using Student's t-test and ANOVA Friedman test. Test U Manna-Whitney was used for the cases that did not have a normal distribution. Chi-squared test was used for evaluation of categorical data. The level of statistical significance was set at $p<0.05$.

RESULTS

There were no significant differences in age and body mass index between two groups. Four patients did not complete the follow up schedule and thus were excluded from the study, leaving a total of 15 patients in TVT and 16 patients in TVT-O group. One of them was lost in follow up and three had bladder perforation during TVT procedure and were excluded from the trial. After perforation, which was confirmed in cystoscopy, the tape was removed.

Effectiveness of each procedure was measured subjectively. To estimate this outcome VAS was used, and resulted in statistical improvement of SUI symptoms regression in both groups measured after 3 and 6 months (Figure1). However, there was no difference in VAS, comparing TVT vs. TVT-O groups. There was no difference in subjective ailments corresponding to SUI before the operation between two groups (p=0,564). We observed statistically significant reduction in subjective estimation of ailments corresponding to SUI after 3 and 6 moths from operation in TVT group and TVT-O group. However, the difference between both groups was statistically insignificant (p-value=0,956 and 0,873 respectively).

We observed statistically significant improvement in subjective assessment of health condition in each group after 3

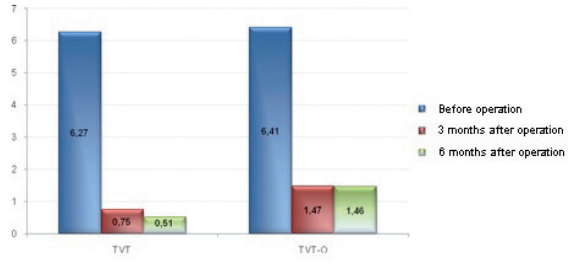

Figure 1. – Comparison of subjective effectiveness of both procedure, TVT and TVT-O, before, after 3 and 6 months from operation. For this purpose Visual Analogue Scale (VAS) was used.

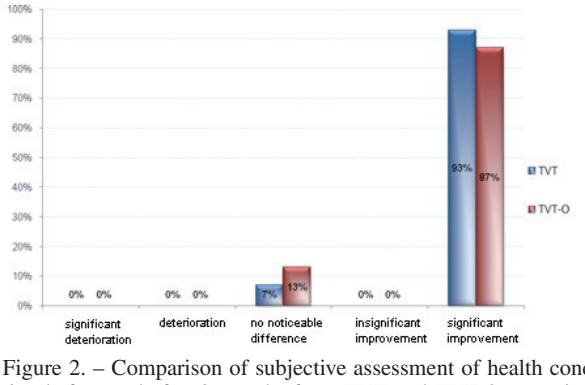

Figure 2. – Comparison of subjective assessment of health condition before and after 3 months from TVT and TVT-O operations. Significant improvement of health condition took place in 93% of women after TVT operation and in 87% TVT-O group.

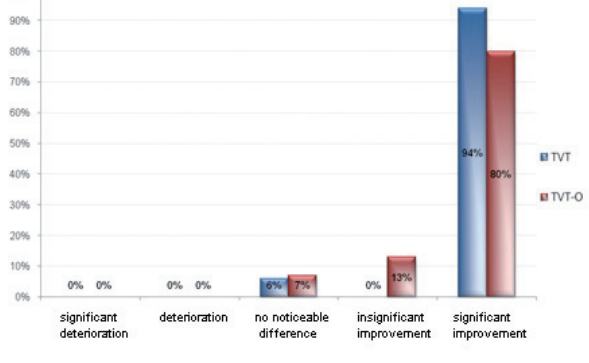

Figure 3. – Comparison of subjective assessment of health condition before and after 6 months from TVT and TVT-O operations. Significant improvement of health condition took place in 94% of women after TVT operation and in and in 80% TVT-O group.

and 6 months from operation (Figure 2, Figure 3). However, when we compared both groups, the difference was not statistically significant (p-value=0,95 and 0,37 respectively).

There were no statistical differences between two procedures after 3 and 6 months in the results of cough test in standing and recumbence position (after 3 months p value in standing position p=0,59, in recumbence position p=0,96; after 6 months p value in standing position p=0,26, in recumbence position p=0,51).

The pad test was performed before and after 6 months from operation and significant improvement was achieved. In the TVT group the test was negative in 94% patients after operation, and in TVT-O in 87% patients. The difference was statistically insignificant (p=0,51).

Both groups showed improvements in all aspects (Table 1, Table 2) in postoperative questionnaires, KHQ and SF-36. There were no significant differences in the quality of life (Table 1, Table 2) in both procedures.

There were no statistical differences between two groups in perioperative complications and late complications, however there were 3 cases of bladder perforation in TVT group (18%) (Table 3)

The average procedure time was shorter in TVT-O group (12,4 min (SD=3,52) vs. 47,75 min (SD=42,89)) and the difference was statistically significant (p<0,001). Also average operation time was shorter for TVT-O group (39,25 min (SD=10,19) vs. 71,35 min (SD=48,73)) with statistical significance difference between two procedures (p=0,001).

There was no statistical difference between two groups in the time of hospitalization (p=0,578). Average hospitalization time in TVT group was 2,41 days (SD=1,37), for TVT-O group it was 2 days per each patient (SD=0.0).

DISCUSSION

This prospective, multicenter, randomized single blinded trial was designed to compare the use of TVT and TVT-O in surgical treatment of stress urinary incontinence. At 6 months' follow up, we demonstrated that TVT and TVT-O seem to be equally effective in SUI surgical treatment, which is consistent with results of others trials,[15] but not all of them,[16] in which TVT operation was more efficient than TVT-O or TOT in treating SUI. Effectiveness, which was measured in our trial subjectively and objectively, did not differ between both groups. Subjective evaluation was the primary outcome and resulted in improvement of SUI symptoms regression in both groups measured after 3 and 6 months. Objective effectiveness was also estimated after 3 and 6 moths by pad and cough tests and resulted in improvement of SUI symptoms regression. The differences were insignificant between both groups. When we asked patients for subjective estimation of ailments corresponding to SUI and subjective assessment of health condition before and after 3 and 6 months from operation, we found improvement in both aspects in TVT and TVT-O group, but we did not find differences between them. Noteworthy, none of the patients in both groups reported deterioration of general health after 6 months of the operation. When we compare both procedures, there were no differences in each domain of KHQ or SF-36 questionnaire in the quality of life.

We think, as the others, that advantage in TVT-O operation is that retropubic space is avoided, which reduces the risk of bladder, bowel or major vascular injury or perfusion. Although many reports confirmed excellent cure rates for TVT, the complications associated with blindly entering the retropubic space, might be limitation of this procedure.[17] With TVT-O procedure many of these problems are avoided. Several recent studies have demonstrated that the incidence of perioperative and short-term postoperative complications associated with the TVT-O procedure is low.[18] On the other hand, what is also critical, retropubic TVT procedure required less operative time and results in shorter hospitalization time, with significantly less postoperative pain and faster return to regular daily activities than the traditional Burch colposuspension.[19] In our trial, bladder perfusion occurred in 3 TVT patients' (18%). None of these complications occurred in TVT-O group. However, bladder perforation usually has no long-term adverse consequences.[20] Despite that, we did not notice any differences in early and late complications between the two groups.

Probably, due to the fact that cystoscopy was necessary to verify bladder injury during TVT procedure, the operation

TABLE 1. – Scores of each domain of the King's health questionnaire before and after 3 and 6 months follow-up in TVT and TVT-O groups. Statistical improvement was achieved in a TVT-O group in all domains of KHQ after 3 and 6 months from operation. In a TVT group statistical improvement was achieved in almost all domains of KHQ after 3 months (except general health perception (p=0,110) but in all domains of KHQ after 6 months from operation time.

KHQ Domain	Preoperative score (mean (SD))			Three months postoperative score (mean (SD))			Six months postoperative score (mean (SD))		
	TVT	TVT-O	p-value	TVT	TVT-O	p-value	TVT	TVT-O	p-value
General health perception	37,5 (15,5)	32,4 (17,1)	0,314	26,7 (25,8)	14,1 (15,7)	0,129	13,9 (15,4)	20 (16,9)	0,287
Incontinence impact	75,9 (22,3)	82,4 (31,4)	0,186	22,2 (37,1)	31,3 (37,5)	0,413	18,5 (30,7)	17,8 (30,5)	0,965
Role limitations	63,9 (23,7)	68,6 (31,7)	0,417	13,3 (21,1)	17,7 (29,5)	0,886	10,2 (19,1)	13,3 (23,7)	0,721
Physical limitations	76,9 (24,3)	82,4 (33,1)	0,355	26,7 (15,2)	32,3 (28,8)	0,948	24,1 (18,3)	28,9 (25,6)	0,731
Social limitations	42,5 (30,2)	39,9 (32,4)	0,767	0,9 (3,1)	11,8 (21,6)	0,101	0 (0)	4,8 (12)	0,057
Personal relationships	36,7 (29,7)	39,2 (38,6)	0,969	2,6 (9,2)	6,7 (17,6)	0,384	1,2 (4,5)	11,1 (24,1)	0,275
Emotions	56,8 (24,7)	50,3 (32,9)	0,453	8,7 (12,5)	19,4 (31,3)	0,814	6,8 (17,1)	12,6 (22,6)	0,419
Sleep/energy	46,3 (24)	37,3 (23,2)	0,263	10,7 (14)	13,5 (20,4)	0,944	9,3 (14,3)	10,7 (14)	0,692
Severity measures	69,9 (12,8)	67,7 (26,5)	0,903	25 (26,9)	25,5 (28,8)	0,936	25,6 (25,3)	27,4 (31,3)	0,965

Table 2. – Scores of each domain of the SF-36 questionnaire before and after 3 and 6 months follow-up in TVT and TVT-O groups. Statistical improvement was achieved in a TVT-O group only in physical functioning (p=0,003) and PCS (p=0,024). After 6 months statistical improvement was also achieved in a physical limitations (p=0,012) and social functioning (p=0,026). In TVT group, questionnaire performed after 3 months, reveal that statistical improvement was not achieved only in general health domain (p=0,224) and pain feeling (p=0,182). After 6 months from operation there were no changes in SF-36 questionnaires statistical analysis (p=0.328 and p=0,170 respectively for general health and pain feeling).

SF-36 Domain	Preoperative score (mean (SD))			Three months postoperative score (mean (SD))			Six months postoperative score (mean (SD))		
	TVT	TVT-O	p-value	TVT	TVT-O	p-value	TVT	TVT-O	p-value
Physical functioning	49,2 (19,6)	52,1 (27,8)	0,529	88,4 (14)	82,6 (25,1)	0,722	89,4 (18,4)	79,1 (26,8)	0,123
Physical limitations	47,2 (45,3)	58,8 (43,2)	0,488	87,5 (28,9)	79,4 (38,8)	0,487	94,4 (18,3)	92,6 (24,6)	0,929
Pain feeling	71,5 (27)	73,5 (29,5)	0,685	82,8 (21,6)	81,2 (27,9)	0,892	87,8 (25,7)	83,8 (26,3)	0,470
General health	60 (17,4)	61,6 (25,1)	0,466	67,1 (16,7)	69,7 (25,3)	0,368	70 (18,3)	68,4 (25,1)	0,850
Vitality	51,8 (14,1)	57,1 (25,1)	0,226	71,8 (13,5)	68,2 (27,3)	0,905	69,7 (14)	69,4 (29,3)	0,511
Social limitations	61,8 (20,8)	64 (34,5)	0,484	92,2 (11,1)	77,2 (27,7)	0,122	91 (16,5)	86 (25,3)	0,579
Emotional limitations	70,4 (39,4)	64,7 (44,8)	0, 854	93,8 (25)	74,5 (43,3)	0,096	92,6 (24,4)	88,2 (28,7)	0,587
Sanity	56,2 (18,9)	62,8 (27)	0,132	72 (16,9)	71,8 (26,1)	0,591	77,2 (14)	71,3 (26,5)	0,641
MCS	59,9 (17,4)	62,1 (29,7)	0,270	81,9 (11,8)	72,9 (28,4)	0,889	82,4 (13,7)	78,7 (25)	0,863
PCS	57 (17,3)	60,7 (26,1)	0,343	80,4 (15,5)	78,2 (26,5)	0,450	85,4 (16,8)	81 (23,8)	0,406

Table 3. – Peri- and postoperative complications (although cystoscopy was not used for TVT-O group, we have assumed that no bladder perforation occurred in TVT-O group, because we recorded no signs suggesting this complication (p=0,39 when comparing two groups)). There were no symptoms suggesting vaginal, bladder or urethral erosion. There were no bowel, nerves or major vessels injuries. To sum up, perforation of the bladder, urinary retention and hematoma appear to be bore often after TVT operation, but with no statistical difference between both groups.

	Perioperative complications			Postoperative complications after3 months			Postoperative complications after 6 months		
	TVT	TVT-O	p-value	TVT	TVT-O	p-value	TVT	TVT-O	p-value
Infection (other than urinary tract infection)	0(0%)	1(6%)	0,76	1(7%)	0(0%)	0,74	0(0%)	1(7%)	0,75
Bladder perforation	3(18%)	0(0%)	0,39	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Urinary retention	1(6%)	0(0%)	0,76	2(15%)	0(0%)	0,49	1(6%)	0(0%)	0,77
Hematoma	2(12%)	0(0%)	0,56	3(21%)	0(0%)	0,33	3(19%)	0(0%)	0,37
Pain	0(0%)	2(13%)	0,54	6(46%)	4(27%)	0,38	2(13%)	1(7%)	0,78
Bleeding	3(18%)	0(0%)	0,4	3(21%)	5(33%)	0,59	0(0%)	0(0%)	1

and procedure times were longer, which is related to results of others.[21]

Till today there is only one meta-analysis in literature, which compares TVT and TVT-O procedures.[10] For this analysis 15 RCTs that compared both procedures were included. When direct comparison was made, subjective and objective cure rate did not differ between both groups (OR 1.06, 95% CI 0,85-1.33 and for objective cure rate OR 1.03, 95% CI 0.77-1.39). When patients with only SUI were analyzed, subjective cure rate in 8 trials reached OR 1.03 (95% CI 0.81-1.31). The TVT-O had fever complications of bladder injury but more groin pain and de novo urgency than TVT. The primary outcome in most trials was 'cured' and this was measured and reported in various ways. Most, but not all studies reported on subjective cure rates and only some defined objective cure rate. Advantage of our study is that we analyzed both of them using appropriate methods (VAS for objective cure rate and pad or cough test for objective cure rate) to estimate effectiveness of each operative method.

There are some strengths and limitations of our study. Based on published data, our study is the first single blinded trial comparing TVT vs. TVT-O. The one study comparing surgical techniques in SUI treatment, TVT-O vs. TOTARIS[22] started as single blinded but ended because of an ethical issue. This is one of few trials so far that compares both subjective and objective effectiveness of TVT or TVT-O in surgical treatment of SUI.

Another advantage of our study is wide and very restrictive inclusion criteria, which also resulted in small number of patient in each group and is primary limitation of this study. A recently published randomized study, demonstrated that patients with severe SUI had significantly better outcome after TVT compared to TVT-O, suggesting that severity of SUI is an parameter that can influence the results of

sling operations.[23] Additionally, patients with previous surgery for SUI or pelvic reconstruction may carry a higher risk of postoperative urine retention or procedure failure, when they are treated with TVT or TVT-O procedure.[24] As mentioned before, in our trial, only pure-SUI patients, confirmed in urodynamic exam, were recruited. It was very important, because in one study it was found, that patients with SUI had a persistent cure rate of 85% from 2 to 8 years after TVT surgery, whereas the cure rate of patients with mixed urinary incontinence steadily declined to 30% from 4 to 8 years after surgery.[25]

Long-term follow up is required and is under way to ascertain long-term validity of our results. Adequate randomization, concealment and low patient withdrawal are also without fail strengths of this trail.

To conclude, this prospective randomized single blinded study shows no significant difference in the early and late operative complications, objective and patient-reported success rate between TVT and TVT-O procedures in SUI surgical treatment at 6 months follow up. On the other hand 18% of operating patients from TVT group had bladder perforation, even that it was not statistical different between both procedures, it makes a difference for a patient. Undoubtedly, TVT-O had shorter operation and procedure time for no need of routine cystoscopy.

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Is tolterodine as effective as oxybutynin in overactive bladder caused by spinal cord injury?

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Abstract: Abstract: In neuro-urological practice the immediate release oxybutynin - the extended release one has become available in Italy only in 2010 - is usually considered more effective than the immediate release tolterodine in the treatment of overactive bladder caused by spinal cord injury. But in literature there is no a clear evidence, mainly for lack of papers on this topic.
We reviewed records of patients with spinal cord injury from January 1996 and June 2009. We found 16 patients (11 males and 5 females, mean age 43.5 years, range 22-67) that switched the antimuscarinic treatment from one drug to the other one having been checked by videourodynamic examinations during the assumption of each drug. The drugs were assumed at the usual dosages (tolterodine 2 mg twice a day and oxybutinin 5 mg twice or three times a day with an average of 12.5 mg). The efficacy of the antimuscarinics has been estimated clinically, based on the micturition diaries, and instrumentally, based on the modifications of the urodynamic parameters. Oxybutynin has resulted more effective than tolterodine at the recommended dosage for 75% of patients with detrusor-sphincter dyssinergy caused by sovrasacral spinal cord injury. Videourodynamic studies showed an increase of cystometric bladder capacity and a decrease of detrusor pressure in comparison with tolterodine. The statistical comparison between the two averages relative to maximal detrusor pressure and bladder cystometric capacity determined by using the "Student test for data joined to a tail" has turned out meaningful for p<0,01.

Key words: Antimuscarinics; Neurogenic bladder; Spinal cord injury; Urodynamics

INTRODUCTION

Many neurourologists consider oxybutynin (OX) more effective than tolterodine (TL) in the treatment of the overactive bladder caused by the sovrasacral spinal cord injury (SCI) in the picture of the detrusor-sphincter dyssinergy (DESD). In DESD the antimuscarinics are usually used to abolish detrusor contractions in order to permit voidings by clean intermittent catheterism (CIC). However, in literature there is no a clear and well established evidence although these drugs were mainly compared in idiopathic overactive bladder or in a few and different types of neurogenic overactive bladder.[1-8]

In Italy the extended release OX has become available only in 2010. On the other hand the immediate release OX is still nowadays the main antimuscarinic agent used for neurogenic bladder as the generic drug is dispensed free of charge by the National Health System to the SCI patients. Therefore we reviewed the records of the SCI cases referring to our departments in order to identify the patients who switched the immediate release antimuscarinic therapy – from TL to OX or otherwise – and who underwent videourodynamic studies during the assumption of each drug.

MATERIALS AND METHODS

Between January 1996 and June 2009 16 patients have met our inclusion criteria: they should have been treated in different times with OX and TL, they should have undergone urodynamics during the assumption of each drug and the urodynamic examination should have been performed at least 2 month after the beginning of the assumption of each antimuscarinic agent (see tab. 1).

All the patients presented DESD caused by at least a two year stabilized sovrasacral SCI and all of them had to change the therapy in use: 11 patients discontinued OX, and changed with TL, for comparison of side-effects (moderate/severe dry mouth in 10 patients and tachycardia in 1) while in 5 subjects TL assumption was interrupted, and replaced by OX, as TL wasn't effective in the cure of the urinary incontinence. The drugs were assumed at the usual dosages: TL 2 mg twice a day and OX at the dose of 5 mg twice or three times a day (average of 12.5 mg/die).

Thirteen patients voided by self-CIC while 3 women, at the beginning treated with TL, voided by reflex micturitions. The videourodynamic examination was carried out at least 2 months after the assumption of each drug (range 2-13 months, mean 3.8) and it was performed in the lytotomic position using one double-lumen transurethral catheter 6 Ch and one rectal probe. Iodinated contrast medium was infused at a flow rate of body weight/4 ml/min and a Medtronic Duet system was used. Urinary sterility and regularity of urinary tracts by ecography were checked previously. For all patients the micturition diaries of 4 days were available.

The effectiveness of the therapies has been estimated: a) clinically, based on the micturition diaries and on the urinary leakages; b) instrumentally, based on the modifications of the urodynamic parameters.

A "t of Student for data joined to a tail" test was applied to compare the different values of maximum cystometric capacity and maximal detrusor pressure during treatments with OX and TL. Statistically significant difference was accepted for $p < 0.05$.

TABLE 1. Patients' features

	M	F	tot
patients n.	11	5	16
age at lesion	37,1(22-61)a.	30,1(23-62)a.	34,9(22-62)a.
age at observation	45,6(26-64)a.	38,6(24.64)a.	43,4(24-64)a.
cervical level	2	1	3
thoracic level	9	4	13

RESULTS

Clinical data

In 12 patients (75%) OX improved the storage bladder symptoms in comparison with TL: 9 of them complained urinary incontinence only during the therapy with TL while 3 patients were incontinent with both the drugs but the urinary leakages worsened during the treatment with TL. Also the voided volumes increased during the treatment with OX (9-46% more than with TL, with an average of 26%).

Four patients were unchanged with both the drugs and 2 of them, complaining urinary leakages, underwent detrusorial injections of botulinum toxin.

OX caused complete urinary retention in 2 women that previously voided by reflex micturitions.

Urodynamics data

All the patients showed DESD with normal compliance and hypo-anestesia of the bladder. None showed vesicoureteral reflux or major radiological alterations.

The average maximum cystometric capacity was 253 ± 126 ml with TL against 323 ± 111 ml observed during OX treatment: therefore OX increased the maximum cystometric capacity of 80 cc (38%) in average, respect to TL. All the values are shown in fig. 1. The statistical comparison between the two averages executed with the test "t of Student for data joined to a tail" has turned out meaningful for $p < 0,01$.

The maximal detrusor pressure was reduced by OX: from an average of 43.5 ± 24.4 cm H2O with TL to an average of 31.2 ± 16,7 (range 0- 53 cm H2O less, mean 12.3 corresponding to a mean percentage decrease of 19% - see fig. 2). The statistical comparison between the two averages executed with the test "t of Student for data joined to a tail" has turned out meaningful for $p < 0,01$.

In 4 patients (25%) urodynamic data were the same during both the therapies.

In conclusion a situation of low-pressure bladder – assuming a cut-off for maximal detrusorial pressure < 30 cm during cystometry – has been reached in 9 patients during OX treatment and in 4 subjects during TL therapy.

DISCUSSION

There exists only limited literature on the use of antimuscarinics in patients with neurogenic incontinence.

The overactive bladder caused by sovrasacral SCI is a suitable model to compare the effects of antimuscarinic drugs since the detrusor contraction is reflex in such patients and it is not influenced by psychological inhibition. But, on the other hand, it is really problematic to compare antimuscarinics in randomised or prospective trials in such patients for ethical reasons.

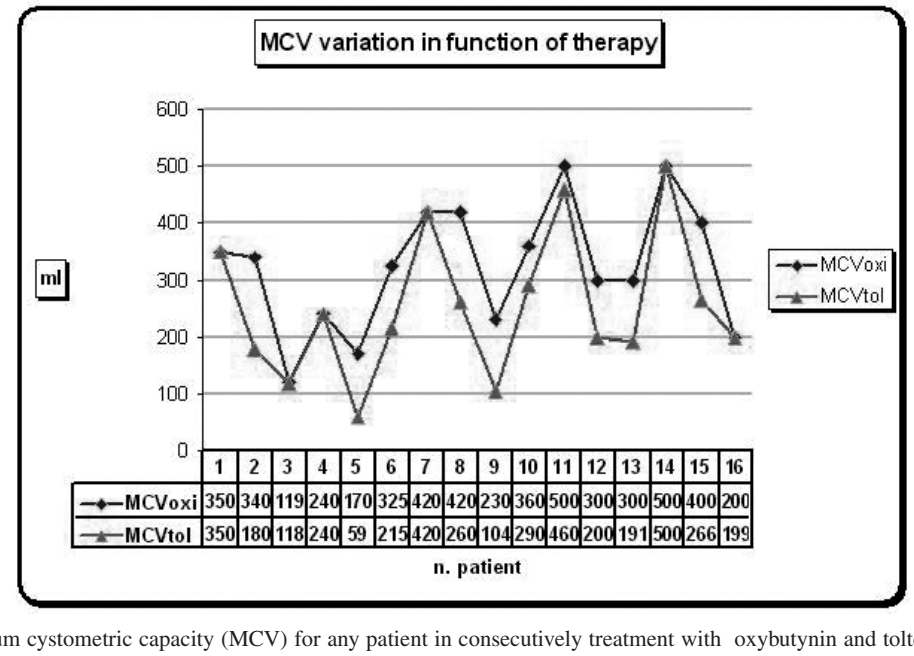
OX generally causes a significantly higher incidence of adverse events than TL[4,7,10] and this feature have been greatly underlined in last years. Especially the frequent dry mouth induced by OX, reported in 30-60% of cases based on different series, has led to find alternative drugs and TL has been the molecule more used in 1990s, even though few studies proved its efficacy in neurogenic overactive bladder.[2,6,11].

In a randomised study including 33% SCI patients, Van Kerrebroeck and all showed that TL was more effective than placebo in treating the symptoms of overactive bladder and that the therapeutic effect was dose-dependent.[1]

Later only Ethans[2] compared OX and TL in 10 patients with neurogenic overactive bladder – in 7 of them caused by SCI – but in self-selected doses regimen. He reported that the efficacy of TL was comparable to OX in enhancing bladder volume, improving continence and cystometric bladder capacity but OX presented a worse side effect profile (dry mouth). In this study larger doses of TL have been used to achieve this effect: TL twice daily at the average dose of 8 mg has been compared with OX twice daily at the usual average dose of 12.5 mg.

Further Horstmann[3] suggested to double TL and trospium chloride doses in neurogenic overactive bladder not responding to the usual dosages. Two doses of extended release TL, 4 mg and 8 mg respectively, were compared and a significant amelioration of urodynamic parameters with the higher dosage was observed.

In the last years Cameron[4] and again the group of Horstman[5] proposed to combine two or more antimuscarinics in neurogenic bladder resistant to monotherapy.



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
MCVoxi	350	340	119	240	170	325	420	420	230	360	500	300	300	500	400	200
MCVtol	350	180	118	240	59	215	420	260	104	290	460	200	191	500	266	199

Figure 1. – Maximum cystometric capacity (MCV) for any patient in consecutively treatment with oxybutynin and tolterodine.

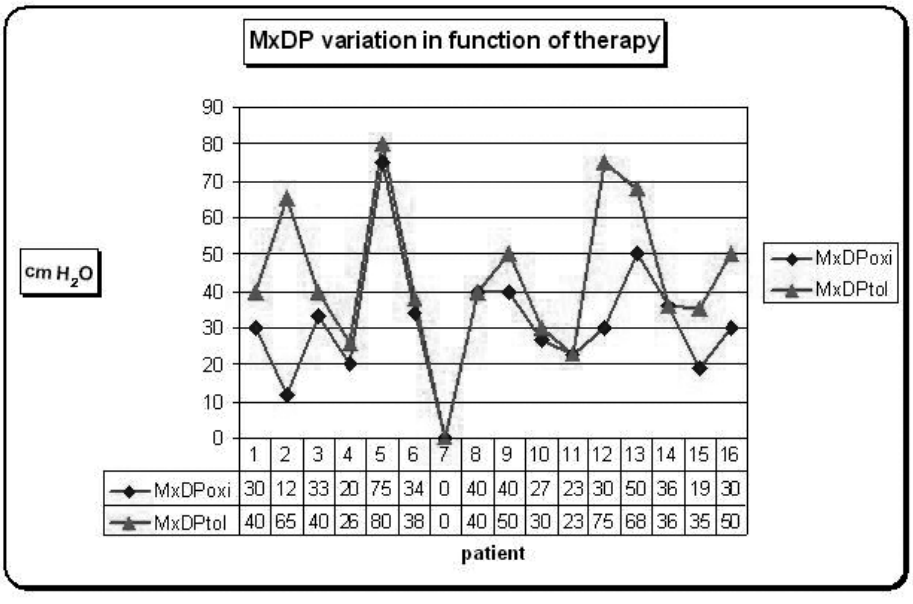


Figure 2. – Maximum detrusor pressure (PMax) for any patient in consecutively treatment with oxybutynin and tolterodine.

Many SCI patients referring to our neuro-urological departments assume OX and most of them are satisfacted. We reviewed all our records and we found a little and homogeneous group of sovrasacral SCI patients who assumed in different times the immediate release forms of TL and OX at usual dosages and who were checked instrumentally during both the therapies. Even though the usual methodological and ethical limits in studies regarding SCI patients – the studies are mainly retrospective and based on a small number of patients – the higher efficacy of OX was observed in 75% of cases both clinically – disappearance of urinary incontinence and enhancing voided volumes – than instrumentally with a mean increased of 38% as regard the cystometric bladder capacity and a mean percentage decrease of 19% of maximum detrusor pressure. Therefore the usual dosage of TL shouldn't be used in overactive bladder due to SCI except than in patients who void by reflex micturitions in a safe way and in whom a reduction of urgency is searched (but low dosages of OX could also be used in these rare situations). In our opinion in case of adverse events caused by OX it is better to prescribe trospium chloride or detrusorial injections of botulinum toxin rather than TL.

CONCLUSIONS

The immediate release OX is still the reference antimuscarinic drug in SCI patients in Italy as it effectiveness is well-supported by daily activity and the literature.

In our experience OX has proven to be more effective than the immediate release form of TL for 75% of SCI patients with detrusor-sphincter dyssinergy.

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Original article

Conversion from abdominal sacrocolpopexy to vaginal surgery with transobturator mesh placement in the treatment of vaginal vault prolapse

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Abstract: Vaginal vault prolapse may be treated by laparoscopic or abdominal sacrocolpopexy or by vaginal suspension procedures. Laparoscopic sacrocolpopexy that prove to be too complex can be completed via an abdominal approach. This is the first report in the literature of conversion from abdominal sacrocolpopexy to vaginal surgery with synthetic mesh insertion via the transobturator route.

Key words: Pelvic organ prolapse; Vaginal vault prolapse; Transobturator mesh; Sacrocolpopexy; Conversion.

INTRODUCTION

Pelvic organ prolapse affects an estimated one-third of women,[1] of whom 0.5% have clinically significant post-hysterectomy prolapse.[2] Treatment may be administered via the laparoscopic, abdominal, or vaginal approach. Laparoscopic or abdominal sacrocolpopexy is preferred because of the low morbidity and high success rate.[3-5] The reported rate of intraoperative conversion from laparoscopic to abdominal sacrocolpopexy is about 2%.[6] The main reasons for conversion are organ laceration, bleeding, or severe pelvic adhesions.

We report, for the first time, conversion from abdominal sacrocolpopexy to vaginal surgery with transobturator mesh placement for the treatment of vaginal vault prolapse.

CASE REPORT

A 71-year-old woman presented with a bulge from the vagina of 5 years' duration. Her medical history revealed 3 previous vaginal deliveries. She had undergone vaginal hysterectomy with posterior and anterior colporraphy 6 years previously for the treatment of uterine prolapse and anterior and posterior wall prolapse. She was also receiving medical treatment for high blood pressure and diabetes type 2. She had never smoked or received hormonal replacement therapy.

The suspected recurrent pelvic organ prolapse was evaluated according to the Pelvic Organ Prolapse quantification (POP-Q) system, as recommended by the International Continence Society [7]. Findings revealed stage 2 apical prolapse, stage 3 anterior wall prolapse, and stage 3 posterior wall prolapse. There was no stress incontinence on reduction of the prolapse. After receiving a detailed explanation of the treatment protocol, the patient provided written informed consent to undergo abdominal sacrocolpopexy with abdominal mesh placement combined with bilateral salpingooophorectomy and posterior colporrhaphy.

The surgical team was led by an experienced surgeon in abdominal sacrocolpopexy procedure. Preoperative antibiotic prophylaxis consisted of cephazolin 1 g and metronidazole 500 mg. The operation was performed under general anesthesia via an abdominal median longitudinal incision from the umbilicus to the symphisis pubis. After the peritoneum was opened, severe adhesion of the omentun and small bowel to the pelvis was noted. Meticulous adhesiolisis was performed, including bilateral salpingo-oophorectomy. However, the severe bowel adhesions and the excessive bleeding from the adhesion site necessitated careful hemostasis and prevented the completion of abdominal sacrocolpoplexy. Following consultation with the main author, (H.K), it was decided to convert to a vaginal procedure with placement of the mesh implant via the trans-obturator route in order to overcome the severe adhesions. Anterior and posterior mesh kits (Prolift™, Ethicon, USA) were used for this purpose. Vaginal prolapse repair with transobturator kits has been performed in our unit since 2006. The surgery was conducted by the first author (H.K.) applying the technique described by Fatton et al. [8], a midline incision was made which included the full thickness of the vagina. There were no significant vaginal adhesions. The vagina was closed after mesh placement with a continuous running Vicryl 2.0 suture, without resection of any vaginal tissue. The postoperative course was uneventful. At the 2-year follow-up, vaginal examination revealed no apical or posterior wall prolapse and asymptomatic stage 1 posterior cystocele. The patient had no urinary symptoms. She complained of constipation that she managed successfully with natural fiber.

DISCUSSION

Pelvic organ prolapse is a common problem in women and may cause significant morbidity and a decreased quality of life. The incidence of posthysterectomy vaginal vault prolapse repair after hysterectomy is 0.5%.[9]

Abdominal sacrocolpopexy is a definitive treatment option for vaginal vault prolapse, with durable success rates. It is associated with fewer recurrences and less dyspareunia than vaginal sacrospinous fixation,[4] although morbidity is higher than with vaginal repair. Many of the complications of abdominal surgery are related to the presence of severe abdominal and pelvic adhesions from previous abdominal surgery. The most common intraoperative complications are bleeding from an injured medial sacral artery, cystotomy, enterotomy and ureterotomy. Early postoperative complications include wound infection, ileus, and urinary tract infection, and late complications, stress urinary incontinence, anterior or posterior vaginal wall descent, recurrence of vaginal vault prolapse, and mesh erosion through vaginal wall. Laparoscopic sacrocolpopexy provides the same outcome for abdominal sacrocolpopexy, with less morbidity. The conversion rate from laparoscopic to abdominal sacrocolpopexy is about 2%.[6] Most surgeons prefer to use polypropylene mesh as the suspension structure because of its low rates of infection and other complications compared with other materials.

New vaginal mesh kits have been recently introduced to surgically treat apical, anterior, and posterior wall prolapse. Their use makes it easier for the surgeon to avoid the presacral vessels intraoperatively. Compared to conventional prolapse repair, vaginal transobturator mesh placement is associated with higher cure rate, fast recovery time, and rapid return to activities of daily living although the clinical significance of the improved anatomical results is still unclear.[9-11] A randomized controlled trial yielded fewer anatomic failures at 12 months after vaginal-mesh insertion than after standard vaginal surgery. However, the decrease in symptoms and improvement in quality of life were equal in both groups.[11] Nevertheless, the main disadvantage of using a standardized, trocar-guided mesh kit for prolapse repair is a higher short-term rate of surgical complications and postoperative adverse events.[10-12]

In the patient described here, abdominal prolapse surgery had to be completed by a vaginal approach with the mesh kit because of severe pelvic adhesions that included the small and the large bowels. This successfully prevented adhesiolisis and intestinal damage. The vaginal surgery itself was relatively uneventful and not significantly different from primary vaginal procedures for prolapse repair. The severe abdominal adhesions had no effect on the vaginal dissection. We performed a full-thickness wall incision so that the mesh could be inserted under the fascia, thereby lessening the risk of erosion. We routinely recommend the regular use of vaginal estrogen cream to all patients after mesh insertion.

In conclusion, vaginal surgery for vaginal vault suspension with the use of a trans-obturator mesh kit should be considered when abdominal or laparoscopic approach are suspected to be difficult because of severe abdominal or pelvic adhesions.

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Original article

Urinary and anal incontinence after childbirth in primiparous women: A multicentric study

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Abstract: Aims of the study: to estimate the prevalence of urinary and anal incontinence and their impact on women's quality of life, and to identify the constitutional and obstetric factors significantly related to urinary and anal incontinence. Materials and methods: Data were collected from a cohort of 960 nulliparae (full term delivery 37-42 weeks). Each woman was evaluated both at 2-3 days post-partum and at three months follow-up with: the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Wexner's CGS continent grading system. Results: 161 women revealed persistent urinary incontinence, 121 women persistent anal incontinence and 43 women both conditions together. Concerning constitutional risk factors, positive family history of incontinence and incontinence before and during pregnancy were significantly related to urinary and anal incontinence 3 months post-partum. For obstetric factors the vaginal delivery is a strong risk factors for UI. Conclusions: Many constitutional variables were found to be significantly related to both faecal and urinary incontinence. The vaginal delivery is undoubtedly the more important and recognized obstetrical risk factor for urinary incontinence, while the caesarean delivery did not assume any protective role in the development of anal incontinence

Key words: Urinary stress incontinence; Postpartum; Risk factors.

INTRODUCTION

Perineal dysfunctions, including urinary and anal incontinence and pelvic organ prolapse, are one of the most important problems affecting public health because of their high prevalence and costs[1] and the impact on women's social and psychological life. The literature of last twenty years[2-5] suggests a strong relation between childbirth and the development of perineal dysfunctions at both short and long term. However controversial data exist[6-15] due to the difficulties underlying the retrospective studies and/or to the cohort of subject often being not homogeneous or too small. Thus, to date, these data do not allow to clearly correlate the obstetric events with perineal dysfunctions. Our study aims to a) estimate the prevalence and severity of urinary and anal incontinence and their impact on women's quality of life, b) identify the constitutional and obstetric factors significantly related to urinary and anal incontinence.

MATERIALS AND METHODS

The present observational prospective study, involving six public hospitals in various geographical areas of Italy, was conducted in the period between April 2005 and November 2006 and approved by the relevant Ethical Committees of each participant centre. Data were collected from a cohort of 960 nulliparae (full term delivery 37-42 weeks). Each woman was evaluated both at 2-3 days post-partum and at a 3 months follow-up with the following tools:

- a structured questionnaire investigating age, occupation, smoking habits, presence of chronic cough, constipation, weight before pregnancy, family history of urinary or anal incontinence, weight increase during pregnancy, management of labour, way of delivery and newborn's weight;
- the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)[16] to assess the urinary incontinence and its impact on women's quality of life. Urinary incontinence was defined with a score of at least 3 at the ICIQ-SF;
- the Wexner's CGS continent grading system[17] to assess anal incontinence, defined with a score ≥ 1;

Association between individual risks factors and incontinence (urinary and anal) at 3 month was evaluated by chi-square test. Results were expressed as "*Odds ratio*" (OR: is used to assess the risk of a particular outcome if a certain factor is present) for each variable with confidence limits set at 95% (CL 95%).

RESULTS

For this study we considered a cohort of 960 nulliparae (947 singleton and 13 twin pregnancies) with a mean age of 29.8 years (SD ± 5.6 years) and a mean body mass index (BMI) of 23.9 (SD ±4.5).

Obstetric characteristic and management of the 960 women (Table 1) included 592 women with vaginal delivery, and 368 caesarean section. At the analysis of the data obtained during the immediate post-partum evaluation, urinary and anal incontinence were observed in 327/960 (34.1%) and in 255/960 (26.6%) women respectively. At the 3 months follow-up, 216 patients did not turn-up for their scheduled visit and therefore 744 (70.9%) women were included for final analysis. One hundred sixty-one women revealed persistent urinary incontinence, 121 women persistent anal incontinence and 43 women both conditions together. Urinary incontinence occurred in pregnancy for the first time in 85 (52.8%) out of the 161 women, anal incontinence in 30 (25%) out of 121 women. Stress urinary incontinence was found to be the most common type of urinary incontinence in women, both post-partum (65%) and

TABLE 1. – Obstetric characteristics and management of the 960 women.

Gestational Age (mean ± SD)		39.5±1.5
Physiologic labour (%)		253 (26%)
Induced labour (%)		222 (23%)
	Prostaglandins	124 (13%)
	Oxytocine	41 (4%)
	Amniorrhexis	57 (6%)
Labour active treatment		306 (32%)
	Oxytocine	141 (14.6)
	Amniorrhexis	136 (14%)
	Oxytocine + Amniorrhexis	29 (3%)
First stage of labour		
	min (95%CL)	243 (229-258)
2nd stage of labour		min
<30		323
30-60		197
61-120		56
>120		11
Vaginal Deliveries		592 (62%)
	Spontaneous	541 (56%)
	Vacuum	47 (5%)
	Forceps	1 (0.1%)
	Shoulder dystocia	3 (0.3%)
Caesarean section		368 (38%)
elective		179 (18.7%)
during labour		189 (19.7%)
	Dystocia of labour	68 (7%)
	Faetal causes	121 (12.7%)
Position during delivery		
	gynaecologic	504 (88.7%)
	in water	2 (0.3%)
	free	17 (2%)
	missing	51 (9%)
Episiotomy	Medial	36 (8%)
	Mediolateral	404 (92%)
Birthweight (mean±SD)		3265±460

at 3 months. In terms of severity of urinary incontinence this was mild with a modest impact on quality of life, the median value of ICIQ-SF in incontinent women was 6 (range 3-18) at the 3 months follow-up In addition in 113/121women (84%) at follow-up the median value of Wexner's score was 2 (range 1-9). Table 2 shows the correlation between urinary or anal incontinence in relation to different constitutional and obstetric variables expressed as p values, odds ratios and 95% confidence intervals at univariate analysis. Age > 35 years, constipation, chronic cough, smoking, family history of urinary incontinence, and develop of incontinence before and during pregnancy were significantly related to urinary incontinence 3 months postpartum. Among obstetric factors the vaginal delivery is the strong risk factors for UI. Family history of anal incontinence, incontinence before and during pregnancy, episiotomy resulted significantly related to anal incontinence. An intact perineum resulted to be protective for both urinary and anal incontinence. When univariate analysis on the 3 months data was performed only in women who delivered vaginally showed that physiologic labour played a protective role in the development of urinary incontinence, whereas episiotomy resulted as a risk factor for the development of anal incontinence, as shown in Table 3.

Multiple logistic regression was finally performed to identify those variables that resulted as indipendent predictors of UI and AI in the post partum. Incontinence during pregnancy was confirmed an independent risk factors for UI (OR 3.0 (95% CI 2.4-6.1) and AI (OR 2.2 (95 CI 1.1-4.4). Obesity, (OR 2.68; (95% CI 1.14- 6.32), family history of incontinence (OR 2.41; 95% CI 1.26- 4.59), vaginal delivery (OR 5.85; 95% CI2.10- 16.29) were all confirmed as independent risk factor for UI three months after childbirth.

DISCUSSION

The present observational prospective study is, to date, the most relevant Italian study in terms of size of the cohort of women involved. At the 3 months follow-up urinary incontinence was still evident in 21% of women, the prevalence of anal incontinence was 16% (12% reported flatal incontinence, 3.2% liquid incontinence and only 1.1% solid incontinence). The entity of symptom was mild with a modest impact on quality of life. Many constitutional variables and especially the family history of incontinence were found to be significantly related to both anal and urinary incontinence. The presence of incontinence during pregnancy is highly predictive of postpartum persistent urinary and anal incontinence. The physiologic labour has a protective role while the induction of labour seem to be a risk factor for the development of urinary incontinence. The vaginal delivery was undoubtedly the more important and recognized obstetrical risk factor for urinary incontinence, while the caesarean section did not assume any protective role in the development of anal incontinence. An intact perineum represents a crucial protection factor for the development of anal incontinence. The most interesting and original finding of our study was that 58% of women with urinary incontinence and 33% of women with anal incontinence three months after delivery develop the symptoms during pregnancy. These findings provide a further confirmation that pregnancy is a crucial moment for developing pelvic floor dysfunctions.[2-6] In conclusion, also in agreement with previous papers[11,19] the detection of symptoms of incontinence already in the early post-partum period could be predictive of their persistency and worsening in the near future. The identification of constitutional and obstetric risk factors for pelvic floor should be considered in the routine clinical activity in order to improve our practice and implement a primary and secondary preventive counseling. Efforts in preventing and early treating these conditions are therefore mandatory to improve the overall patient's quality of life.

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TABLE 2. – Risk of urinary or anal incontinence in relation to different constitutional and obstetric variables 3 months after delivery (univariate analysis, chi squared test).

	Urinary incontinence			Anal incontinence		
	OR	**95%C.I.**	**P**	**OR**	**95%C.I.**	**P**
Age >35	1.60	(1.04-2.57)	**0.03**	1.29	(0.75-2.24)	n.s.
Pre-pregnancy BMI	0.99	(0.65-1.37)	n.s.	1.42	(0.95-2.13)	n.s.
Familiarity	2.56	(1.61-4.00)	**<0.001**	2.38	(1.41-4.00)	**0.001**
Constipation	1.70	(1.01-2.86)	**0.047**	1.11	(0.59-2.09)	n.s.
Chronic cough	3.03	(1.43-6.25)	**0.002**	1.09	(0.41-2.94)	n.s.
Smoking	1.75	(1.14-2.78)	**0.010**	1.11	(0.64.1.95)	n.s.
Hard job	0.89	(0.45-1.77)	n.s.	0.76	(0.34-1.73	n.s.
Incontinence before pregnancy	8.1	(3.7-17.4)	**<0.001**	4.3	(2.2- 8.2)	**<0.001**
Incontinence during pregnancy	4.6	(3.1-6.8)	**<0.001**	3.6	(2.2-6.1)	**<0.001**
Weight increase (>12 kg)	1.17	(0.80-1.70)	n.s.	1.10	(0.72-1.70)	n.s.
Labour						
Physiologic	0.97	(0.63-1.50)	n.s.	1.37	(0.86-2.18)	n.s.
Induced	0.99	(0.63-1.57)	n.s.	1.18	(0.70-2.00)	n.s.
With active treatment	1.50	(0.97-2.53)	n.s.	0.69	(0.40-1.18)	n.s.
Pelvic phase (duration in min)*	–	–	n.s.	–	–	n.s.
Mode of delivery Vaginal/Caesarean	3.28	(2.04-5.26)	**<0.001**	1.18	(0.75-1.82)	n.s.
Perineum						
Intact	0.51	(0.32-0.84)	**0.007**	0.41	(0.22-0.78)	**0.005**
Laceration (1st - 2nd degree)			n.s.			n.s.
Episiotomy	1.59	(1.04-2.43)	**0.03**	2.91	(1.60-5.30)	**<0.001**
Birth weight (> 3800 grams)	1.41	(0.72-2.75)	n.s.	0.88	(0.45-1.70)	n.s.
Head circumference (> 35 cm)	1.48	(0.77-2.82)	n.s.	1.02	(0.46-2.26)	n.s.

* evaluated as a 3x2 table, OR not applicable

TABLE 3. – Obstetric risk factors at univariate analysis for urinary and anal incontinence at 3 months after delivery in women who delivered vaginally.

	Urinary incontinence			Anal incontinence		
	OR	**95%C.I.**	**P**	**OR**	**95%C.I.**	**P**
Labour						
Physiologic	0.58	(0.37-0.92)	**0.02**	1.34	(0.79-2.26)	n.s.
Induced	1.04	(0.64-1.70)	n.s.	1.06	(0.59-1.88)	n.s.
With active treatment	1.56	(0.98-2.46)	n.s.	0.69	(0.439-1.21)	n.s.
Pelvic phase (duration in min)*			n.s.			n.s.
Perineum						
Intact	1.43	(0.63-3.25)	n.s.	0.20	(0.02-1.53)	n.s.
Laceration (1st - 2nd degree)	1.02	(0.59-1.76)	n.s.	1.29	(0.61-2.73)	n.s.
Episiotomy	0.70	(0.40-1.23)	n.s.	4.70	(1.44-15.60)	**0.005**

* evaluated as a 3x2 table, OR not applicable

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Original article

Prospective study on 185 females with urinary incontinence treated by an outside-in transobturator suburethral sling

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Abstract: Objectives To assess the placement and efficacy of a low elasticity TOT (Aris) in the long term and to compare it with the other techniques. *Patients and methods:* This is a prospective study. Between 2004 and 2008, 185 patients were included. They were suffering from pure or mixed stress urinary incontinence. All the slings were implanted by the same surgeon according to the same original surgical technique described in 2001. The patients underwent regular clinical follow-up. Outcomes assessed include the efficacy on SUI and urgency, de novo dysuria and urgency, per and post-op complications, the impact of sphincter deficiency and bladder instability. The average median follow-up of our patients is 23 months. *Results:* The long-term results on continence are 91.2% at over 36 months. There is no degradation of the efficacy over time. A rigorous surgical technique minimizes the risk of complications. The urinary urgency is cured or improved in 74.3% of cases in the long-term. Lower level efficacy of the transobturator sling in the case of sphincter deficiency is confirmed. The de novo dysuria rate is 4.4%. *Conclusion:* This study confirms the efficacy, reproducibility, and the safety of the transobturator technique.

Key words: Female Stress Urinary Incontinence; Transobturator Tape (TOT); Hypo elasticity; Urinary Urgency.

INTRODUCTION

In 2001 we described and published information on the first group of patients treated for stress urinary incontinence by the implantation of a transobturator sling to treat stress urinary incontinence (SUI).[1] The initial objective of the transobturator sling was to use synthetic tape to reproduce the suburethral fascia described by Delancey.[2] In 1998, we used suburethral slings sutured to the obturator external muscle, at the level of the tendinous arch on both sides of the urethra. In 1999 we used the "tension-free" suspension proposed by Petros et Ulmsten[3] with a passage through the obturator hole to maintain the sling in place. In 2003, anatomical work led by Delmas led us to definitively privilege the outside-in technique which anatomically speaking presents less of a risk of a pudendal nerve and obturator lesion.[4,5] From the very beginning of experimentation with the transobturator route, it seemed preferable to us to use low elasticity synthetic mesh to facilitate suburethral adjustment and to avoid using the sheaths that are required for the insertion of the elastic slings. To meet the low elasticity criterion, the first transobturator slings were made of hot-welded monofilament polypropylene. This mesh proved to carry a high risk of infection and vaginal erosion.[6-8] In 2004, we abandoned the use of hot-welded mesh in favour of a macroporous, knitted, polypropylene mesh with reduced elasticity, low grammage and good shape memory (no cupping), the ARIS® Transobturator Sling (Coloplast Corp.).

In this article we will report on the first group of patients treated for SUI using TOT/ARIS, operated on by the same surgeon.

MATERIALS AND METHODS

Between 2004 and 2008, 305 patients were enrolled in a prospective study of the TOT-ARIS sling device. All patients had pure or mixed SUI, positive cough stress test results, and had failed perineal re-education. Patients were excluded from the study if they had previously undergone related surgery (hysterectomy or prolapse treatment). Based on the above criteria, 185 patients were included in the study. The slings were all implanted according to the same original technique described in 20011 and modified in 2005.[9]

Patients were seen pre-operatively, at 3 months, at 1 year and then every year post-implant. Follow-up over 36 months was available for 68 patients. All the patients have been clinically evaluated using the Measurement of Urinary Handicap (Table 1) in the pre-operative phase and during all subsequent outpatient visits. Pre-operative Urodynamic Assessment (PUA) was systematic. The sling used was the ARIS® Transobturator Sling (Table 2). The ancillary equipment was a re-steriliziable Emmet needle with a foam tip. The majority of the patients were operated on under spinal anaesthesia (82%), more rarely under a general anaesthetic and exceptionally, under a local anaesthetic (n=1).

RESULTS

Our results are summarized in Tables 3, 4 and 5. Table 3 presents the pre-operative condition of the patients and tables 4 and 5 present patient follow-up. The average median follow-up of our patients is 23 months. For 68 patients follow-up has been demonstrated for greater than 36 months. Stress urinary incontinence (SUI) was cured (MUH=0) in 85.3% of cases and was improved in 91.2% of cases. Six patients required tightening of the sling by surgical plication at a distance from their first operation and all of them were continent after the plication operation (MUH=0). Patients suffering from sphincter deficiency (urethral pressure (UP) < 30 cmH_2O) were cured after 3 months in 71.4% of cases, whereas patients with a UP > 30 cmH2O were cured in 89.8 % of cases. At over 36 months, 55.5% of the patients with sphincter deficiency were cured, compared with 84.1% in the absence of sphincter deficiency.

Pre-operatively, 90 patients suffered from mixed urinary incontinence (MUI) and 19 from an SUI combined with urinary urgency without leakage. Among the urinary urgency patients in the pre-operative phase, with (urge urinary incontinence (UUI)) or without leakage, urinary urgency was cured in 51.4% of cases, improved in 22.9% and unchanged in 25.7% of cases. No urinary urgency was worsened by the surgery.

At 3 months, 11.3% of the patients suffered from de novo urinary urgency (of which half were with leakage, thus, 5.6% of those with de novo UUI). At 36 months, the total amounted to 17.6% of de novo urinary urgency (of which half were with leakage, in other words 8% of UUI de no-

TABLE 1. – Mhu scale.

Score	**0**	**1**	**2**	**3**	**4**
Urgency (Deadline of safety)	No Urgency	10-15 minutes	5-10 Minutes	2-5 minutes	< 2 minutes
Urge Urinary incontinence (number of leakage)	No UUI	Once a month	Several time a month	Several time a week	Several time a day
Day time frequency (number of hours between two voids)	> 2	1,5-2	1	0,5	< 0,5
Night time frequency	0-1	2	3-4	5-6	>6
Stress urinary incontinence	No SUI	Violent effort (sports...)	Average effort (cough, sneeze, laughter...)	Low effort (walking...)	Lesser effort
Other incontinence/enuresis	No other incontinence	Once a month	Once a week	Several time a week	Once a day
Dysuria	No Dysuria	Terminal dribble	Straining	Feeling of incomplete emptying	Catheterisme

TABLE 2. – Physical characteristics of the aris® sling.

Materiel	Knitted monofilament polypropylene
Weight	78g /m2
Thickness	0,3mm
Diameter of the fibres	80µm
Size of the mesh	550*170 µm
Elasticity	7,5%
Resistance	55N
Maximum elongation %	72%
Sheath	NO
Particles released	<0,3%

TABLE 3. – Pre-operative condition of patients.

	Number	**Average**	**%**
Number of patients	185		
Patient characteristics Ages		59.09 (31-89)	
Weight (Kg)		70.9	
BMI		27.2	
Height (cm)		162	
Parity		2.2	
ATCD hysterectomy	28		15
ATCD cure prolapsus	11		6
ATCD cure of SUI	9		4.8
Gesture associated with the TOT	0		0
Symptoms			
SUI alone	77		41.6
SUI with urge urinary incontinence without leakage	90		48.6
Mixed UI	18		9.8
SUI MUH 1	5		2.6
SUI MUH 2	31		16.7
SUI MUH 3	142		76.6
SUI MUH 4	8		4.2
Clinical Dysuria	31		16.7
Diurnal overactive bladder (>8 urinations)	38		20.5
Nocturnal overactive bladder (>2 urinations)	59		31,9
Pre-operative PUA			
Qmax< 15ml/s	12/182		6.6
Qmax> 15ml/s	170/182		93.4
RPM≥ 75 ml	5/179		2.8
Closing pressure Urethral < 30 cmH_2O	17/177		9.6

vo). Of the patients with urinary urgency seen past 36 months, 5.8% had not urinary urgency at 3 months. Hence, their urinary urgency de novo appeared at a later stage.

The de novo dysuria rate (MUH stages 2 to 4) amounted to 3.3% at 3 months and 4.4% at over 36 months. The patients cured of their stress incontinence (MUH=0) and who had no de novo dysuria accounted for 96.8% at 3 months and 96.6% at 36 months.

There were no per-operative complications and no immediate revision surgery was performed. There were 23 immediate post-operative complications. Intermittent catheterization (Clavien II) involved a total of 16 patients. For 14 of them, the catheterization was necessary for less than 10 days. For 2 patients, catheterization continued for 3 and 24 months respectively and was then stopped. Two patients suffered from EVA>3 (Clavien I) post-operative pain. The same two patients continue to suffer from chronic pelvic pain. Four patients suffered from urinary tract infections and one patient suffered from pyelonephritis (Clavien II). There were no cases of late onset serious complications (urethral or vaginal erosion).

DISCUSSION

The per and post-operative complications rate in our group of patients is lower than that of the literature (table 6).

Anatomic surgical descriptive studies[5] have already demonstrated the theoretical low risk of the passage of the sling during the course of its implantation. The absence of bladder wounds is to be found in the literature, apart from in the Porena[10] group that presents a rate of 1.33%. The anatomical study[5] shows that there is a minimal distance of 15 mm between the upper edge of the ischiopubic branch and the insertion of the levator ani muscle on the internal obturator muscle on which the bladder rests. The needle must go in under the obturator insertion of the levator ani muscle in order to not harm the bladder. If the needle is passed in contact with the ischiopubic branch and if when it leaves the bone contact it directly meets the finger introduced into the vaginal incision in the sub-pubic lateral ure-

TABLE 4. – Results at 3 and at 36 months.

	Follow-up at 3 months		**Follow-up at > 36 months**	
	Number	**%**	**Number**	**%**
Number	177		68	
Satisfaction				
Very satisfied	142	80.3	43	63
Satisfied	30	17	18	26.6
Unchanged	5	2.7	4	5.8
Regrets	0	0	3	4.2
Stress Continence				
MUH 0	155	87.5	58	85.3
MUH 1	9	5.1	2	3
MUH 2	8	4.5	3	4.4
MUH 3	5	2.8	5	7.3
MUH 4	0	0	0	0
Not improved	5	2.8	6	8.8
Worsened	0	0	0	0
Dysuria				
Clinical dysuria patients	8		3	
De novo	6	3.3	3	4.4
Held back	1	0.5	0	0
Intermittent catheterisation	2	1.1	0	0
Overactive Bladder				
Over active bladder patients	10	5.6	5	7.3

** Percentage in relation to the population seen again that was suffering from urge urinary incontinence in the pre-operative phases.*

thral muscle, the needle's journey will be perineal and anatomically, there will be no risk of a bladder lesion.

There was virtually no immediate or delayed (1.1%) post-operative pain. In the literature, secondary pain from out/in TOTs is rare. The study that reports on the most is the Wang[11] study with 12.9% post-operative pain, compared with 0.8% in the David-Montefiore[12] group. The post-operative pain rates in the TVT-O groups are higher, up to over 24 %[13] and 16% for Laurikainen.[14] The lower incidence in the out/in pathway can find its explanation in the anatomical surgical study. Indeed, Delmas, Spinosa and Riedere showed in 2005 that the out/in pathway minimizes the risk of a pudendal nerve and obturator lesion with a shorter journey that is closer to the ischiopubic branch.[15] The type of synthetic prosthesis could also play a role in post-operative pain. For some, prosthetic rehabilitation could be the cause of pain. This has been described for hernia prostheses.[16]

There was no occurrence of urethral or vaginal erosion. It has been demonstrated that the macroporous, knitted, polypropylene mesh prostheses are more effective at preventing vaginal erosion.[17] Clinical trials on the other types of slings (e.g. multifilament polypropylene) report erosion rates and notably vaginal erosion rates that are higher.[18-20] The use of monofilament prostheses does not eliminate the risk.[21]

In our group, the UI cure rate is 87.5% (155/177) at 3 months and 85.3% (58/68) at over 36 months. The improvement rate is 97.2% at 3 months and 91.2% at over 36 months.

TABLE 5. – Results at 3 and at 36 months.

	Follow-up at 3 months		**Follow-up at > 36 months**	
Urge Urinary Incontinence				
Number of patients seen again among those who had urinary urgency in pre-operative	107		35	
Urinary Urgency	70	39.5	29	42.6
Cured	57	32.2; 53.3*	18	26.4; 51.4*
Improved	23	13; 21.5*	8	11.8; 22.9*
Leakage			7	10.3
Without			1	1.47
Remained asymptomatic	50	29.4	19	27.9
Identical to pre-operative phase	21	11.9; 19.6*	9	13.1; 25.7*
Leakage	17	9.6; 15.9*	8	11.7; 22.9*
Without leakage	4	2.2; 3.7*	1	1.4; 2.9*
De novo	18	11.3	12	17.6
Leakage	11	6.2	6	8.8
Without leakage	9	5.1	6	8.8
De novo/ status the same at 3 months			4	5.8
Worsened	3.3; 6	5.6*	0	0;0*
Leakage	5	2.8; 4.7*	0	0;0*
Without leakage	1	0.5; 0.9*	0	0;0*
Tightened since the last surgery	0		1	
Neuromod	0		0	
Complications				
Urinary infections (cystitis)	30		13	
Slings felt at vaginal level during clinical examination	6			
Pain/ Dyspareunia	2		1	
Intermittent catheterisation	2	1.1	0	0
Other	0		0	
Clavien I	8	20	13	7
Clavien II	32	80	1	93
Clavien III	0		0	
Clavien IV	0		0	
Clavien V	0		0	

** Percentage in relation to the population seen again that was suffering from urge urinary incontinence in the pre-operative phases.*

There is no statistically significant difference between the cure rates at 3 months and at over 36 months (p=0.9), nor between the improvement rates (p=0.75) and hence there is no degradation of the UI results over time. These rates are similar to those found in the literature (Table 7).

For our patients, sphincter deficiency was one of the factors that led to failure of the TOT. At 3 months and after 36

TABLE 6. – Per and post-operative complications in the literature.

Group	Number of patients	Haematoma Haemorrhage	Bladder wounds %	Vaginal wounds %	Urinary retention %	Analogical visual scale >3
Castaings T. et Delorme E. 2010	185	0	0	0	0.5	1
TOT						
Barry C. et al. 2008[36]	80	40	0			
Paick JS. Et al. 2007[33]	212		0		6.6	
Porena M. et al. 2007[10]	75		1.33	5.33		
Wang AC. et al. 2006[11]	31	117	0	12.9		12.9
David-Montefiore L. et al. 2006[12]		46	0	0	0	1
Mellier G. et al.2004[37]	94		0			
TVTO						
Zullo MA. Et al. 2007[38]	37	40	0	0	0	
Lee KS. Et al. 2007[39]	60	31	0		13.3	
Andonian S. et al. 2007[19]	78		0		7.8	3.9
Laurikainen E. et al. 2007[14]	131	131				16
TVT						
Barry C. et al. 2008[36]	107	64	8.5			
Zullo MA. Et al. 2007[38]	35	39	5.7	2.7	2.7	
Lee KS. Et al. 2007[39]	60	40	3.3		10	
Paick JS. Et al. 2007[33]	252		4.8		15.1	
Porena M. et al. 2007[10]	73		2.7	0		
Andonian S. et al. 2007[19]	80		13.8		7.5	6.3
Laurikainen E. et al. 2007[14]	136					1.5
Wang AC. et al. 2006[11]	29	125	3.4	0		0
David-Montefiore L. et al. 2006[12]		42		9.5	10.9	2
Mellier[37] G. et al. 2004	99		10			

TABLE 7. – Continence results for the SUIS in the literature.

	Number of patients	Average duration of follow-up (months)	Cure rate %
TVT-O			
Waltregny, 2008[40]	102	36	88.4
Collinet, 2008[41]	984	2	90
Neuman, 2007[42]	300	14	97.3
TOT			
Deval, 2006[43]	129	17	89.9
Roumeguere, 2005[44]	120	12	80
Spinosa, 2005[15]	117	16	92.3
Costa, 2004[45]	183	7	80.5
Delorme, 2001[1]	32	17	90.6

months, there is a statistically significant difference in recovery between those patients with a UP<30 cmH_2O and those with a UP>30 cmH_2O (At 3 months, p=0.016; after 36 months, p=0.0068). These results are corroborated by Clemons JL[22] and Guerette NL[23] who find similar results to ours. For us the TOT is not the gold standard for UI with sphincter deficiency. The results diverge in the literature: Cetinel B[24] and Meschia M 25 do not find sphincter deficiency to be a predictive factor for efficacy.

The cure rate for urinary urgency patients is on average in the literature slightly higher than 50% with an aggravation rate of 10%; however, the studies report recurrence of urinary urgency over time. [26-32] In our group, at 3 months, 53.3% of the patients were cured of their urinary urgency symptoms and 21.5% had improved, hence an efficacy of 74.8%. For patients with over 36 months follow-up, 51.4% were cured and 22.9% had improved, in other words, an efficacy rate of 74.3%. No patient saw a worsening in her symptoms and the efficacy on urinary urgency symptoms remained stable. At the end of our follow-up, we observed a non-negligible rate (17.6%) of de novo urinary urgency, half of which was with urinary leakage.

For Duckett J.R[27] and Choe, J.H[30] the presence of uninhibited contractions at the pre-operative urodynamic assessment is not a risk of failure of the SUI on the urge urinary incontinence symptoms. For Paick J.S.[33] and Laurikainen E.,[28] he presence of bladder instability at the time of the pre-operative urodynamic assessment is a factor for failure. The comparison of the efficacy of our SUIs treatment on the urinary urgency symptoms according to the presence or absence of pre-operative bladder instability did not give rise to any significant differences, neither at 3 months (p=0.56), nor at over 36 months (p=0.70). However, we did not propose the implantation of a sub-urethral sling for those patients suffering from sphincter instability with strong contractions at 15 cm of water.

In our group, the de novo dysuria rate amounted to 3.3% at 3 months and 4.4% at over 36 months. In Latthe's34 meta analysis, the average de novo dysuria rate for TVT-Os is 5.5%, for Monarc® TOTs, 2.9% and for the other TOTs,

2.5%. For the TVTs the average rate is 9.2%. The transobturator route appears to be less impactful regarding dysuria than the retropubic route. The meta-analysis does not reveal any difference regarding post-operative dysuria between elastic slings (TVT-O and Monarc® TOT) and TOT low elasticity slings (elasticity: <10% vs 30%). Nevertheless, the Krauth35 study is in favor of the low elasticity slings (1.5% of post-operative dysuria at 1 year). The efficacy of low level elasticity slings on dysuria remains to be confirmed by other studies.

CONCLUSION

A rigorous out/in TOT surgical technique that relies on sound knowledge of the pelvic anatomy is the best way to prevent per-operative complications as our group shows (a single center experience). Erosion prevention is conditioned by the type of sling used, but also by the technical quality of the surgical gesture. The long and short-term results of our group are in line with those of the literature. SUI is cured in approximately 90% of cases and these results are stable over time. Urge urinary incontinence is cured in 50% of cases. Recurrence of incontinence by de novo urge urinary incontinence occurs in 8.9% of cases. Further study is needed to show a statistically significant reduction of post-operative dysuria followed by the implantation of reduced elasticity slings.

ABBREVIATIONS

SUI, stress urinary incontinence;
TOT, transobturator tape
PUA, Pre-operative Urodynamic Assessment
MUH, Measurement of Urinary Handicap
UP, urethral pressure
UUI, urge urinary incontinence

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Case report

Repair of posterior perineal hernia with biological mesh: a case report

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Abstract: *Introduction*: Perineal hernia is un uncommon and challenging surgical condition characterized by posterior dislocation of the rectum or other intestinal tract through a weak or damaged pelvic floor, causing obstructed defecation and requiring surgical repair by an experienced surgical team. *Methods:* Herein we report the case of a posterior perineal hernia (posterior rectocele) occurred in a patient after surgical drainage of a perineal abscess and causing severe obstructed defecation. After diagnostic work-up, including dynamic defecography and anorectal manometry, the perineal defect was repaired by means of a biological mesh of bovine pericardium. *Results:* The postoperative course was uneventful and the medium term outcome, evaluated by a dedicated severity of disease and quality of life questionnaires, was significantly improved. *Comment:* Use of biological mesh can be useful in the repair of difficult cases of posterior perineal hernia where the risk of infection and direct contact with the viscera makes other choices more risky.

Key words: Pelvic floor hernia; Biological mesh; Perineal hernia; Posterior rectocele.

INTRODUCTION

Pelvic floor hernia is a rare condition, often difficult to diagnose, characterized by the protrusion of intra-abdominal viscera through a defect in the pelvic floor.

The first description of this condition was a case of perineal hernia after a proctectomy.[1] Since then several other cases, with different etiology and modality of care, were published.

Three types of pelvic floor hernias can occur according to the site of pelvic fascial weakness or interruption: obturator, perineal and sciatic hernias.[2] Furthermore perineal hernias may be distinguished in primary and secondary.[3] Primary perineal hernias are extremely rare and generally occur through defects in the pelvic floor musculature. They usually occur between the ages of 40 and 60 years and are five times more common in women due to the larger female pelvis and due to a weakness of the pelvis floor after pregnancy and childbirth.[2] Secondary forms of perineal hernias are incisional hernias occurring in patients mainly after accidental or iatrogenic pelvic injury like in abdominal perineal resection of the rectum or pelvic exenteration for advanced rectal cancer. A large portion of the pelvic floor is removed during these procedures, creating a defect that allows the pelvic organs to descend through the pelvis into perineum.[4] The incidence is estimated about 1% after abdominal perineal resection and 3 to 10% after pelvic exenteration.[3] Secondary perineal hernias also may occur after urogenital and gynaecological operations,[5] usually during the first year after surgery.[3]

Further classification is related to their anatomic position anteriorly or posteriorly in relation to the transverse perineal muscles. The orifice of the anterior form is located in the urogenital diaphgram and this implies that in women clinical manifestation is represented by a prolapse, lateral to the vagina in the area of the labia while the posterior form of perineal hernia is rare and protrudes either through the levator ani muscle or between the levator ani muscle and coccygeus muscle and so the pelvic organs can herniate into the ischio-rectal fossa, becoming evident as an unilateral swelling in the perineal or gluteal region.[6,7] Generally perineal hernias are not symptomatic with the exception of a bulge: at clinical examination there is a soft, reducible and usually uncomplicated bulge which increase its size during Valsalva manoeuvre. Perineal pain, obstructed defecation, perineal skin erosion, perineal fullness and discomfort, urinary symptoms[4] are the most frequently complained in these patients. Clinical complication like strangulation is unusual because the hernia neck tends to be wide and the muscular defect elastic.[7]

CASE REPORT

A 70-year old female patient was visited in our colorectal unit complaining of severe outlet obstructing constipation, and a swelling of the left buttock during straining to defecate. To help defecation she constantly used stimulating laxatives, enemas and manual sustainment of the bulging perineum. Her clinical history included an open cholecystectomy for gallstones, hysterectomy for uterine polyps and perianal incision for the drainage of a left perianal abscess. A rectosigmoidoscopy and a pelvic magnetic resonance showed no evidence of organic disease.

At clinical examination a large defect in the posterior left pelvic floor was evident, due to iatrogenic injury of the levator ani muscles caused by the deep incision for the abscess drainage.

A dynamic colpodefecography using a new contrast medium mimicking the normal stool consistency, specific weight and temperature (Bariogel, THD, Correggio RE, Italy) showed a large non-emptying posterior hernia (rectocele, Figure 1), more evident during straining at defecation which completely prevented rectal emptying. The severity of the defecatory disturbance was scored 20/31 using the ODS (obstructed defaecation score) scoring system[8] and the consequent impairment of the patients QoL (Quality of life) was 95/100 using the SF36 questionnaire,[9] while anal manometry did not show significant alteration of the resting and squeezing anal pressures.

The patient was then submitted to reparative surgery under spinal anesthesia and in Jack-knife position.

A right perianal longitudinal incision was made and the rectum and meso-rectum were exposed. The anococcygeus raphe and the residues of the right levator ani muscles were identified but could not be approximated due to the retraction of the muscles ends and the partial destruction by the previous surgical procedure. A biological, biodegradable 10x10 cm large mesh, Tutomesh®, (imported by Abasan, Bari, Italy) consisting of bovine pericardium tissue was rehydrated by few minutes inclusion in saline solution containing 1 gr of kefalosporin, remodeled according to the

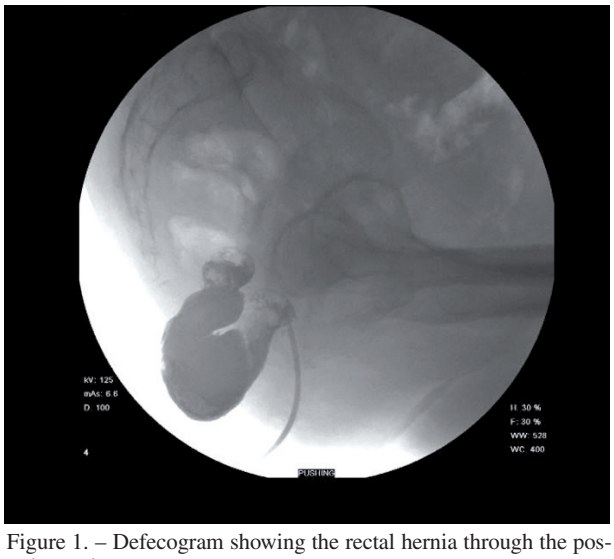

Figure 1. – Defecogram showing the rectal hernia through the posterior perineum at rest.

shape and size of the perineal defect and used to repair the posterior perineum (Figure 2).

The mesh was sutured to the residual muscle-aponevrotic tissue and anococcigeal raphe and to the ischial tuberosity with Prolene 3/0 interrupted sutures. A subcutaneous drainage was placed to prevent a seroma formation. A prophylactic antibiotic therapy was started just before surgery and continued for two days postoperatively. The postoperative period was uneventful and the patient was discharged from the hospital two days after with the prescription to use oral antibiotics for further five days and oral laxatives for at least three months. At three months follow-up the patient showed clear improvement of the defecation with absence of tenesmus and need of digital manoeuvres to empty the rectum. Postoperative score was 7 for ODS and 98 for SF36.

At six month follow-up, however clinical examination evidenced a moderate, but asymptomatic recurrence of the left buttock swelling. The patient complained only little pain in the area of the bulge but the defecation of soft stools was easy and satisfactory.

DISCUSSION

The correct approach to repair perineal hernias is still a challenging surgical problem since the surgical technique and optimal modality of perineal repair has never been established because of the difficulty to perform prospective randomized trials on and adequate number of homogeneous patients because of the rarity of the disease.[7-10] Furthermore the complexity of the anatomy of the pelvic floor and the different aetiology of the disease make comparison between the case reports very uncertain. Furthermore there is also scarce information about long term outcomes. Different approaches for treating perineal hernias have been proposed in the literature: abdominal,[11] perineal,[5-12] combined abdomino-perineal[13-14] or laparoscopic;[15] these different surgical techniques are almost always associated with use of autologous tissues or prosthetic mesh (synthetic or biologic) repair of the pelvic floor defect or to reinforce the muscle weakness. Most of the cases of perineal hernia follow the abdomino-perineal excision of the rectum where the pelvic floor muscles are resected or severely damaged, while in our case the hernia was caused by an inappropriate surgical manoeuvre aimed to drain an abscess in the ischiorectal fossa resulting in the complete interruption of the levator ani muscles on the site of the abscess. This clinical features made the perineal approach the most appropriate to reach the muscle defect without the risk of nerve injury of the abdominal approach. In fact the paramedian incision of the buttock gave immediate and easy access to the muscle defect and to the mesorectum without bleedings. With regards to the reconstructive techniques, like in most of the other cases reported in the literature, it was not possible to approximate the muscle edges and the use of a mesh was mandatory. Nowadays completely re-absorbable biological meshes are available but at higher cost compared to synthetic ones. The choice of an expensive biological mesh was made considering several factors like the direct contact with the viscera, the risk of infection because of the proximity to the anus, the potential high risk connected to re-operation to remove the mesh in case of infection or erosion.

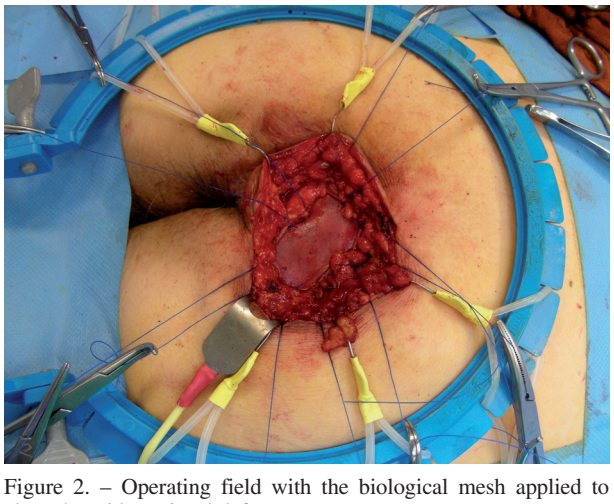

Figure 2. – Operating field with the biological mesh applied to close the wide perineal defect.

Biological meshes have been introduced in the clinical practice with the aim of reducing mesh-related complications but this advantage may be theoretically counterbalanced by a higher recurrence rate. Various complications related to the use of synthetic meshes have been reported including erosion of the viscera, that may occurs early (6 weeks postoperatively) or even many years after surgery, infection with an incidence up to 8%, fistulae, foreign body reaction, fibrosis, calcification, pain, dyschezia etc.[16] Trabuco et al reviewed the MedLine literature about the use of xenograft meshes in reconstructive pelvic surgery both in humans and animal models concluding that due to the poor quality of evidence there is a little evidence supporting the use of biological meshes and that only a good randomized controlled trial with appropriate sample size and long term follow-up can answers the question about the advantages of biologic meshes.[17] Furthermore the few data available are confusing since different types of biological meshes have been used. In fact they can be distinguished between autologous (such as fascia lata or rectus fascia), allograft (like fascia lata or dermis from cadaver) and xenograft (tissues taken from porcine or bovine).[18] The authors report the histological reaction of the host and conclude that the response to xenograft (porcine dermis, bovine pericardium, porcine small bowel submucosa) is similar to the response to synthetic graft. Among xenograft mesh, non-cross linked xenografts are rapidly colonized by fibroblasts and completely replaced by endogenous host connective tissue, and completely resorbed by the host thus obviating the problems related to synthetic materials.[17] Tutomesh belongs to this type of meshes and has good elasticity combined with strong resistance to the pressure and is completely colonized and degraded by endogenous fibroblast within 6-12 months, allowing the host fibroblasts to deposit new collagen and

promote angiogenesis. Furthermore due to its composition it can be placed in contact with the viscera and because of its non-synthetic nature is more resistant to infection. Similar advantages have been reported by other Authors[19] with this bio-resorbable mesh in other parts of the body while the potential higher risk of recurrence has never been documented.

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Case report

Salvage operation for urethral perforation caused by TVT removal for severe urinary incontinence. A case report

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2 University of Western Australia, Crawley-Western Australia

Abstract: Following a TVT midurethral sling 4 years earlier, (initially deemed 85% successful), a 53 year woman presented with gradual deterioration of her incontinence. By mid 2009, the patient was leaking 800-1000 ml/24 hours. There was no urine leak at rest or at night, but she leaked on the slightest effort during the day. On ultrasound examination, the whole posterior urethral wall was opened out during straining, with observed urine loss. The maximal urethral closure pressure was 60cm H2O, with no urodynamically detected detrusor instability. At operation, the urethra was paper thin, 1,5 cm wide, fragile and attached to a wide loose TVT tape partly embedded in the urethral wall. Two small holes were made during tape removal and repaired. A "bridge/flap" of full thickness vaginal mucosa (3x1cm) was brought up to protect the thin urethral wall. A TFS (Tissue Fixation System) adjustable midurethral sling was then inserted over the vaginal flap, then covered by approximation of the lateral vaginal edges to form a double layer. The patient was entirely cured at 12 months review, with no vaginal retention cysts evident. Though midurethral tapes generally enhance the urethral closure mechanisms, a loosely applied tape may fibrose in such a way as to "hold open" the urethra and prevent closure.

Key words: Urethral perforation; TVT; Urinary incontinence.

INTRODUCTION

"Tension-free tape" midurethral slings have now become the gold standard for cure of stress incontinence. However, they are not without complications. Though organ, vascular and nerve damage has been reported, the commonest and most persistent problems concern tape complications which occur in up to 5% of patients in the longer term.[1] Most tape complications consist of vaginal erosions, but urethral and undetected bladder perforations have also been reported. We report severe incontinence 4 years after a "tension-free" midurethral sling, urethral perforation on removal of the tape, and a novel surgical method for simultaneously addressing the damaged urethra and curing the urinary incontinence.

CASE REPORT

A 53 year old para 4 woman had a "tension-free" midurethral sling in May 2006 at another centre for effort urinary incontinence of severe degree. She had a past history of a major co morbidity, a coagulopathy, Von Willebrand's disease plus deficiency in factors 11&12. A 1cm space had apparently been left between the tape and the urethra. She had a post-operative hematoma and required catheterisation post-operatively, but there was no longer term urinary retention or voiding dysfunction.

The operation was according to the patient, 85% successful immediately post surgery, with only mild leaks noted on coughing. These leaks became gradually worse with time until by mid 2009 the patient was leaking a measured 24 hour loss of 800-1000 ml/24 hours. There was no urine leak at rest or at night, but she leaked on the slightest effort during the day, even during a short walk within the house. She had found that the use of transvaginal tampons and external continence pads were the best remedial management, reducing urine loss by approximately one third.

On ultrasound examination during straining, (figure 1), the whole posterior urethral wall appeared to be forcibly opened out. On urodynamic testing, the maximal urethral closure pressure was 60cm H_2O, and there was no bladder instability.

The decision was taken to remove the lower "U" part of the original tape and, because of the patient's bleeding diathesis, it was planned to replace it with a TFS minisling as the least invasive option.

Surgery

At operation, the urethra was paper thin, 1.5cm wide, and tissue fragility was noted at initial dissection. The TVT tape was loose and its "U" section was wide and densely adherent to the urethra. We felt that the anatomical findings precluded a 2nd overlaid tape as the wide tape and fibrosis would not allow sufficient closure, so it was decided to remove the "U" section of the tape. In the process of removal, two small defects, each 0.5 cm in diameter were created in the posterior wall of the urethra. These defects were repaired with fine 4-0 resorbable sutures, using a purse string suture.

A vaginal graft* "G", fig 2, was taken from lower down in the vaginal wall and brought upwards (arrow) to cover the urethra. It was attached to the periurethral tissues with

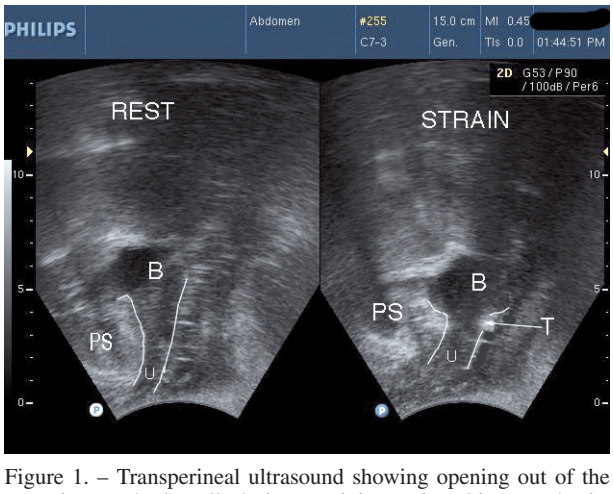

Figure 1. – Transperineal ultrasound showing opening out of the posterior urethral wall during straining. PS=pubic symphysis; B=bladder; U=urethra; T-tape.

LEGENDS
Tape and graft- sagittal view The white ovals indicate the position of the holes.

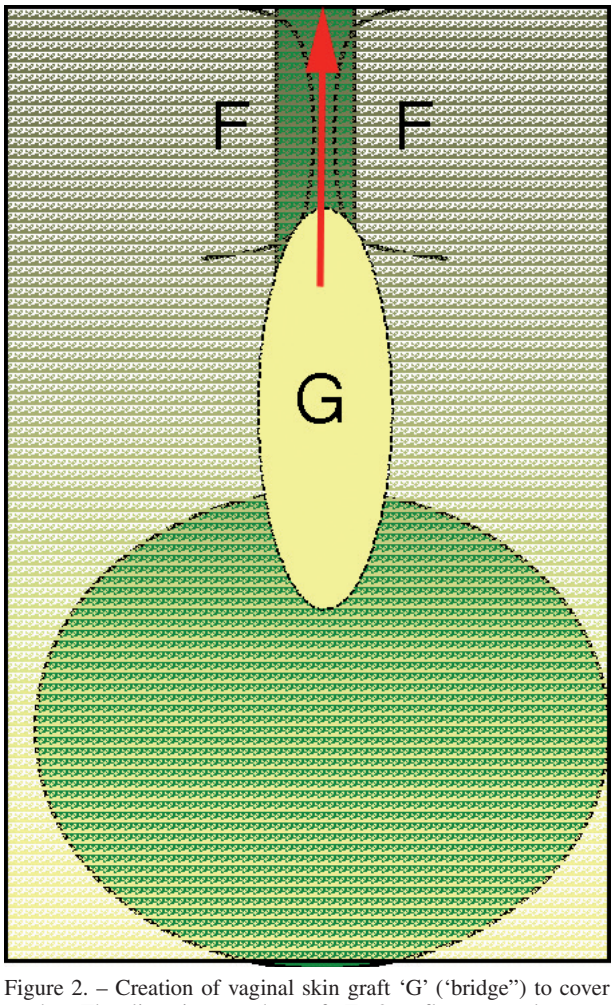

Figure 2. – Creation of vaginal skin graft 'G' ('bridge") to cover urethra. The sling sits over the graft. F= 2cm flaps created to cover the midurethral sling. Arrow indicates how the graft is pulled upwards.

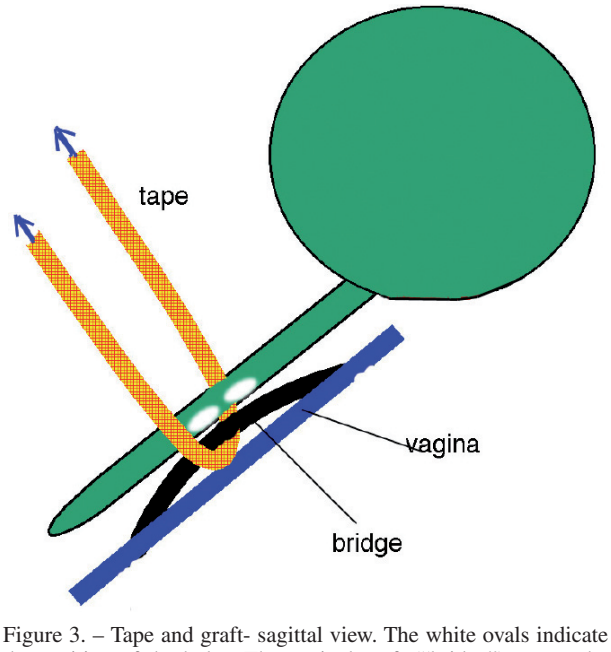

Figure 3. – Tape and graft- sagittal view. The white ovals indicate the position of the holes. The vaginal graft ("bridge") covers the urethra protecting it from the applied tape. Both are overlaid by the vaginal flaps "vagina".

00 resorbable sutures, (fig 2). A TFS (Tissue Fixation System) adjustable sling was then inserted over the vaginal graft at midurethra, fig 3. Prior to tightening the tape, the bladder was filled with 400 ml saline with Methylene Blue to test for any leakage. Valsalva pressure was applied as the tape was adjusted until no leak was apparent prior to approximating the flaps "F", figure 2. A no 8 Hegar dilator was inserted intermittently during tightening to protect against accidental overtightening.

* Known also as a "vaginal bridge" or "bridge technique"

Post-operative course

An IDC silicone 12 Foleys catheter remained in situ for 72 hours. The patient was able to micturate immediately. She was completely continent at 12 months review, with no vaginal retention cysts evident.

DISCUSSION

The anatomical findings were most unusual and influenced our decision to add a protective vaginal layer for the sling. We hypothesize that the post-operative haematoma following the original TVT operation had grossly distorted the sub urethral anatomy, causing stretching of the TVT tape, distension and attenuation of the urethral wall which could not be closed by either the distal or proximal urethral closure mechanisms.4 We believed that the wide adherent TVT tape and extremely thin urethral wall contraindicated an overlaid 2nd TVT tape. Therefore the decision was taken to remove the "U" part of the tape and insert a tissue graft of full thickness vaginal mucosa (3x1cm) to protect the thin urethral wall. The minimally invasive nature of the TFS minisling,2 strong, one-way, precisely adjustable mechanism and a reported 90% cure rate at 3 years,3 suggested that this was a suitable treatment option.

CONCLUSION

The vaginal skin graft provides a simple protective barrier and it allows insertion of a corrective midurethral sling.

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Case Report

Enterocele in a perfectly healthy 59-year old woman: a case report

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Abstract: An enterocele is a loss of vaginal connection to the endopelvic fascia, but it could also be due to congenital defects in the vaginal support, increased intra-abdominal pressure or a wider levator hiatus. This is a clinical presentation of a 59-year old African American woman with no significant past medical history who developed a vaginal enterocele. An exploratory laparotomy was performed and there was a ruptured area approximately 3 cm in size in the posterior cul-de-sac. The remainder of the vagina showed no evidence of any traumatic entry, bruising or hematomas; thus, the prolapsed bowel was reduced back into the abdominal cavity and the defect was repaired. The patient has no previous history of abdominal or pelvic surgeries, no evidence of malignancy seen during the surgery and denied any recent trauma; based on these factors, it still remains a mystery as to why she developed a vaginal enterocele.

Key words: Enterocele; Bowel prolapse; Pelvic organ prolapse; Pelvic reconstruction; Pessary use; Endopelvic fascia; Vaginal support.

CASE PRESENTATION

A 59 year old, African-American woman was admitted to the emergency room, following the development of sudden lower abdominal pain and vaginal bleeding. She is post menopausal and has not had any vaginal bleeding for 10 years. The pain had become progressively worse and is sharp and constant. Patient denies any recent vaginal trauma. Her last sexual intercourse was 2 weeks prior, after which she had no discomfort or vaginal bleeding. She does not have a history of any abdominal or gynecological surgeries. Approximately 2 feet of the small bowel with no evidence of ischemic change had prolapsed out through her vaginal opening (Figure 1). An exploratory laparotomy was performed and there was a ruptured area approximately 3 cm in size in the posterior cul-de-sac. The remainder of the vagina showed no evidence of any traumatic entry, bruising or hematomas. Thus, the prolapsed bowel was reduced back into the abdominal cavity and the defect was repaired. Postoperatively, patient tolerated procedure well and is in stable condition. She has a nasogastric tube placed, continued on IV antibiotics as a precaution to prevent sepsis and anticoagulants for DVT prophylaxis.

DISCUSSION

Nichols and Randall defined enterocele as a lost of vaginal connection to the endopelvic fascia.[1] Others argue that it could be due to congenital defects in the vaginal support, increased intra-abdominal pressure or a wider levator hiatus.[2] According to research, an enterocele can develop due to a significant decrease in the mitochondrial DNA in uterosacral ligaments, as well as, an increase in the rate of apoptosis in women who are suffering from pelvic organ prolapse.[3,4] It was found in one study that women that are older, menopausal and had prior pelvic surgeries are more prone to developing an enterocele.[5] Among these factors however, age is only independently associated with enterocele.[5] Conservative measures such as pessary use are recommended for patients who are unfit candidates for surgery.[6] Otherwise, patients can undergo reconstructive surgeries where they aim to restore normal anatomy and integrity of the endopelvic fascia and its vaginal support.[7]

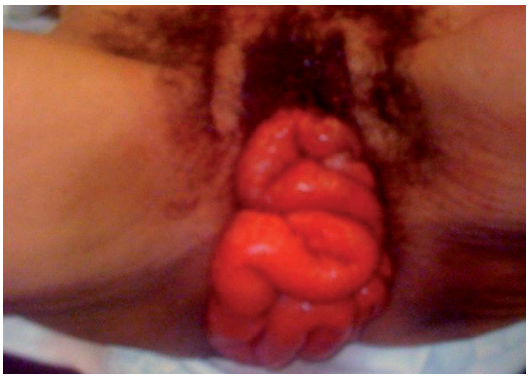

Figure 1. – A loop of small intestine prolapsed through the vagina.

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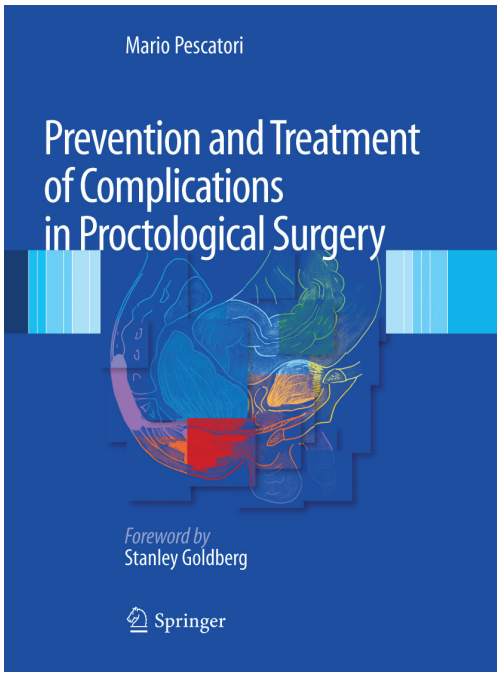
Book review



Prevention and Treatment of Complications in Proctological Surgery

M. PESCATORI, UNIVERSITY OF ROME, La Sapienza, Rome, Italy

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"The volume is authored by a colorectal surgeon with long-standing clinical and scientific experience and is devoted to the management of complications following surgery of the anorectum and the pelvic floor. It is aimed not only at general surgeons, colorectal surgeons, perineologists and, of course, proctologists, but also at gastroenterologists, endoscopists, radiologists, and physiotherapists, i.e. those who may be involved in both diagnosis and cure whenever an adverse event, either unpredictable or potentially preventable, causes an intra- or postoperative, early or late, mild or life-threatening complication. Severe bleeding, dehiscence, perforation, anorectal stricture, fecal incontinence, and even vena cava thrombosis, fatal Fournier gangrene and pneumomediastinum may occur after ano-rectal surgery. The incidence, pathogenesis prevention and treatment of such events are discussed in detail in 10 chapters with 30 tables, 200 illustrations and more than 1000 references. Both conventional procedures and recent innovations are reported. "Unforgettable clinical cases (complications with litigation)" and "Tips and Tricks" are sections increasing the appeal of this book. The approach is "evidence-based" and holistic, focusing on anorectal problems while taking into consideration whole body-mental unity—showing, for example, that a non-healing perineal wound may be due to hypo-pituitarism, and failure after a reintervention may be related to psychological distress".

"Prevention and treatment of complications in proctological surgery" by Mario Pescatori is a quite interesting, useful and also pleasant reading, as it can be expected knowing this *surgeon-writer* who easily becomes a *writer-surgeon* as well.
Of special interest within the field of Pelviperineology, is chapter 8, entitled **"Obstructed Defecation (OD) and Related Diseases"**, where the Author presents all the critical issues of this highly debated topic. The so called "outlet obstruction" or "obstructed defecation" being such a common complaint, the attempts to a "radical", i.e. surgical solution have been very attractive for all surgeons somehow involved with recto-vaginal septum, pelvic organ prolapses, etc. Pescatori analyzes the main surgical procedures, tips, tricks and pitfalls underlying possible complications and how to avoid surgical damages. In order to perform an effectively and safe surgery, it must be kept in mind that OD is never a single dysfunction, and it requires a holistic and multidisciplinary approach. Indeed, in high volume and specialized centres (St Marks Hospital, Cleveland Clinic,…) surgical treatment rates are very low, and patients complaining OD are successfully treated with pelvic floor rehabilitation, biofeedback, high fiber intake diet, and also psychotherapy. A great quote of patients, if carefully asked, admit to be depressed and anxious or both. Very few studies in the literature review the results of treating constipated patients with a psychological approach before surgery.
Using the "iceberg similitude" the author shows how often hidden problems are responsible of symptoms much more than the anatomical defects that surgery is called to correct. Restoring anatomy doesn't imply restoration of a correct function.
New technical devices have been created to improve relatively new surgical procedure. This is the case of the Transtar that, using a Contour stapler, should be the evolution of the well known Starr. The new device should guarantee a better vision of the prolapse, avoiding the blind resection of pph and Starr. So, why complication rate such as rectal bleeding, chronic rectal pain, defecation urgency, urinary retention and recto-vaginal fistula remains notable? Possibly a key of analysis is on careful patient selection and surgeon specialization. Although very often popularized as an easy and safe procedure feasible by general practitioners, stapler surgery requires a precise training, and the general agreement of literature suggests that it should be performed by colorectal surgeons. But even more important is patient selection. Whereas many surgeons are looking for increasing their patients number, poor success results are highly advisable as the satisfactory defecation tends to worsen in time.
Manual procedures such as Delorme, Altemeier or Sarles and Block for rectocele appear to be safer although anastomosis dehiscence may cause pelvic sepsis, bleeding, and complications requiring re-intervention or even a diverting stoma. The same complications may follow the procedure performed for a complete rectal prolapse, in this case indications to surgery cannot be questioned as in case of a functional complaint. The introduction of mesh repair for symptomatic rectocele brought considerable advantages, creating an effective barrier between rectum and vagina. However synthetic meshes are more prone to infections, skin erosion and post-surgical dyspareunia due to a lack of elasticity of posterior vaginal wall.
Reading this chapter we understand how difficult and challenging can be an aggressive treatment of constipation, and, once more, how surgery doesn't always mean cure. We also learn how try to avoid pitfalls and complications due to a too superficial patient's selection and "easy surgery" .

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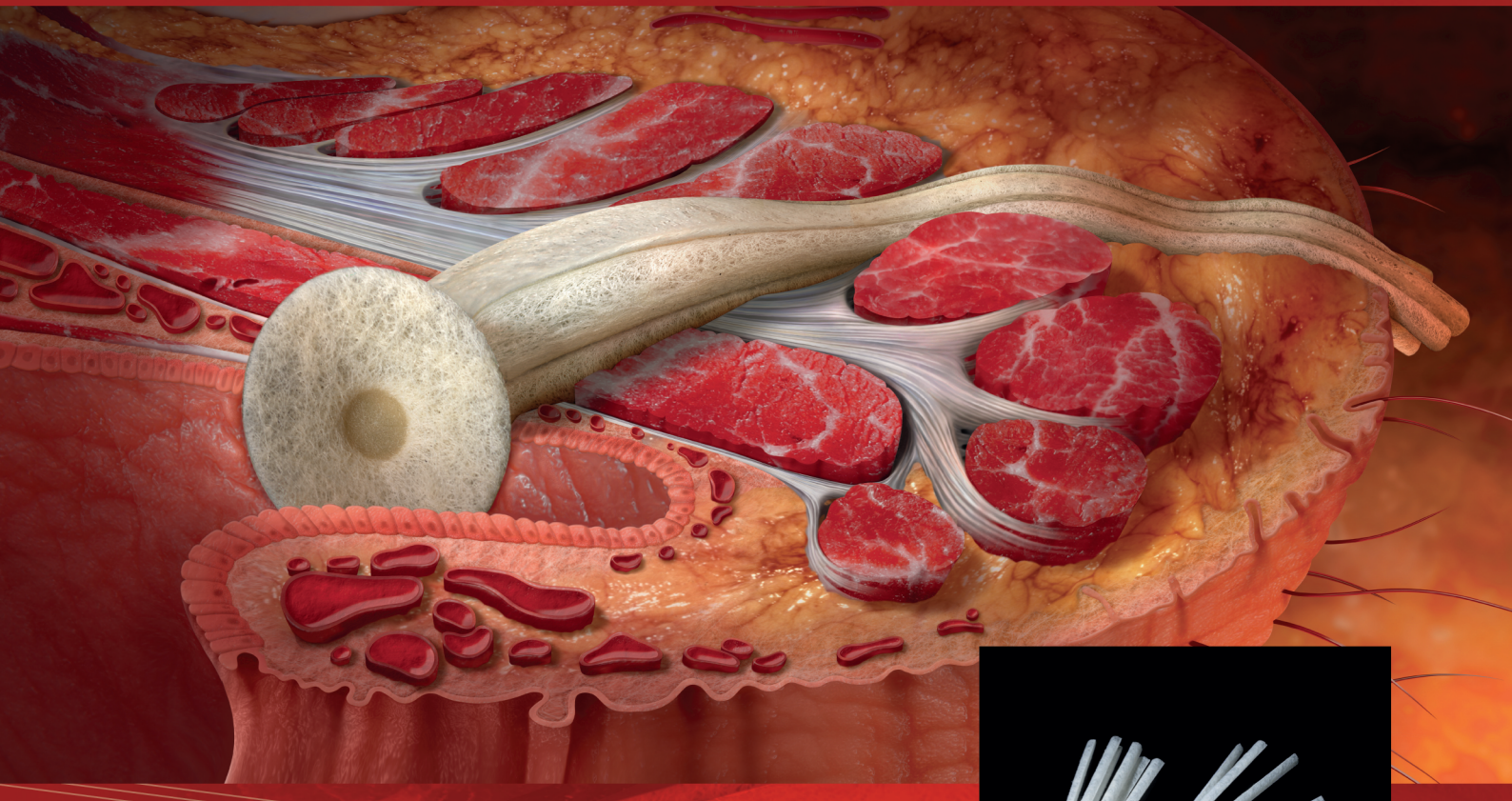

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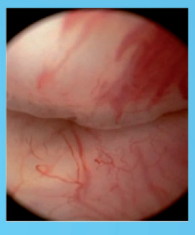


DEXELL® - Implant for treatment of Stress Urinary Incontinence (SUI)

DEXELL is a sterile and viscous gel for the treatment of urinary incontinence caused by stress. It consists of a suspension of dextranomer microparticles and cross-linked hyaluronic acids of non animal origin. The cross-linked hyaluronic acid (Hylan gel) primarily functions as a means of transportation for the dextranomer microparticles which stimulate the connective tissue at the place of injection. Both the Hylan gel as well as the dextranomer microparticles of DEXELL are biodegradable and biocompatible.

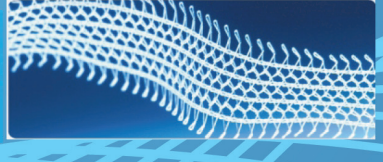
The treatment occurs with the assistance of the special DEXELL implantation system which is inserted into the urinary duct, and which provides a ready position for the hypodermic syringe. Through turning the funnel in a clockwise motion, the implant is then injected equally at four different

HYACYST®

HYACYST is a medical product that consists of a solution from highly purified hyaluronic acid of non-animal origin. It is use for the treatment of INTERSTITIAL CYSTITIS, RECURRENT BACTERIAL CYCTITIS and RADIATION INDUCED CYSTITIS. It is utilised as a sterile rinsing fluid with urothelial changes in the ureter, urinary bladder and the initial portion of the urethra.

HYACYST has no pharmacological effect on the tissue after introduction.

I-STOP®



SUBURETHRAL TAPE FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

The I-STOP is an innovative solution for the treatment of urinary incontinence.

The I-STOP Universal Sling incorporates the proven performance of polypropylene monofilament in a tape specifically designed for pelvic surgery. This unique tape, combined with a choice of needles, makes the I-STOP Universal Sling an ideal solution for virtually any surgical approach for Stress Urinary Incontinence (SUI) treatment in females including transvaginal, suprapubic and transobturator techniques. In addition, the I-Stop Universal Sling is proving to be a successful option for treatment of male SUI and pelvic organ prolapse.

İstem
MEDİKAL TIBBİ CİHAZ VE SANAYİ LTD.ŞTİ.

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